HUMAN
FERTILISATION
&
EMBRYOLOGY
AUTHORITY

FIFTH ANNUAL REPORT – JULY 1996

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HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

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This report covers the year beginning 1 November 1994 with
a forward look for the year beginning 1 November 1995.

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1

The Human Fertilisation and Embryology Authority has been in existence now for five years, having been established in 1991 by the Human Fertilisation and Embryology Act (HFE Act 1990). It continues to be one of the few bodies in the world regulating the practice of reproductive technologies.

Since 1991, medical and scientific advances have been made at a rapid pace. These have provided patients with new opportunities for attempting to have children. New developments in reproductive technology, however, continue to concern the public. One of the tasks of this Authority is to allow new developments to be introduced into clinical treatment only if they are in the interests of the patients and the potential children.

The Authority must keep under review all relevant developments and any new techniques must have the approval of the HFEA before clinics will be licensed to undertake them. In the last year, significant developments have been made in Intra Cytoplasmic Sperm Injection (ICSI) and in Preimplantation Genetic Diagnosis. These are outlined in the sections that follow.

As Chairman of the HFEA, I am very proud of its work. Over the last year, the Authority has analysed and dealt with a number of important issues. As the last Annual Report was published in October 1995, this report is an overview of its activities during the last ten months.

REGULATION

Last year's Annual Report explained why the Authority thought it necessary to review the effectiveness of its system of licensing. This system has now been refined so that a three-year licensing cycle has been introduced and the formal auditing of clinics' treatment data will begin later this year. New HFEA Inspectors have been recently appointed and we look forward to working with them.

The publication of its third Code of Practice in December 1995 has ensured that HFEA licensed clinics and the public are kept abreast of all new or revised HFEA policies.

POLICY AND ETHICAL ISSUES

The Authority has been considering a number of ethical issues over the last year. One is the question of the payment of egg and sperm donors. This is a very topical issue and it is one that has many facets. The Authority has considered the situation carefully over the last two years and it has come to a conclusion which is outlined in Section 7 of this report. Though a change in policy has been agreed, the Authority wishes it to be implemented in a way that avoids any long-term disruptions in provision of service to patients.

The Authority was asked last year by the Secretary of State for Health to provide advice on the issues surrounding the statutory storage period for embryos. The maximum five year storage period for embryos in storage on 1 August 1991, when the Authority took up its powers, comes to an end on 31 July 1996. Our report considered the social, ethical, scientific, legal and practical issues arising from the maximum storage period of five years. I am pleased to say that the Secretary of State accepted, and Parliament brought into force, regulations which reflected the Authority's recommendation that patients should be allowed to store embryos for more than five years provided the appropriate consents have been obtained.

THE PATIENTS' GUIDE

In October 1995, the Authority published its first Patients' Guide to DI and IVF Clinics. This provided the outcomes of DI and IVF treatments in individual clinics for the period 1 April 1993 to 31 March 1994. It has proved very popular with patients and is in constant demand. Although some people criticised the Guide in principle, it was generally welcomed and we received many constructive suggestions from clinicians and patients' groups as to how it could be improved. As a result, some changes have been introduced to this year's Guide which contains data for the period 1 April 1994 to 31 March 1995. We will continue to review it with each annual publication so that it provides the best information possible for patients whilst remaining fair to the licensed clinics.

CONCLUSION

As the HFEA grows in public recognition, the number of national and international requests for information are increasing, from patients, students and the general public. The workload that each Member undertakes each month has certainly grown over the years. I am grateful for the many days of work that they undertake annually on behalf of the Authority and for their commitment to fulfilling the role set for them by Parliament.

I am sorry to report that, inevitably, a number of Members will be leaving the Authority at the end of this year after serving two terms. Each of them helped to set up this Authority, and their hard work and dedication to the Authority and to public service in such a complex and controversial area will be missed. On behalf of the other Members and the staff I would like to thank them and to wish them well.

Another change at the Authority is the departure of our founding Chief Executive, Flora Goldhill, at the end of July. She has served the Authority well as its first Chief Executive. She too will be greatly missed by Members and staff. I would like to take this opportunity to welcome her replacement, Suzanne McCarthy.

The Authority has also recently appointed a number of new Inspectors to its Inspectors' panel. We value the work of our Inspectors highly and acknowledge their significant contribution to the licensing process.

Finally, I pay tribute to all the Members and the staff of the Authority, including those who have departed over the past year. Their hard work, loyalty and sense of purpose are as fine as I could hope to find in any walk of life.

Ruth Deech

RUTH DEECH
CHAIRMAN

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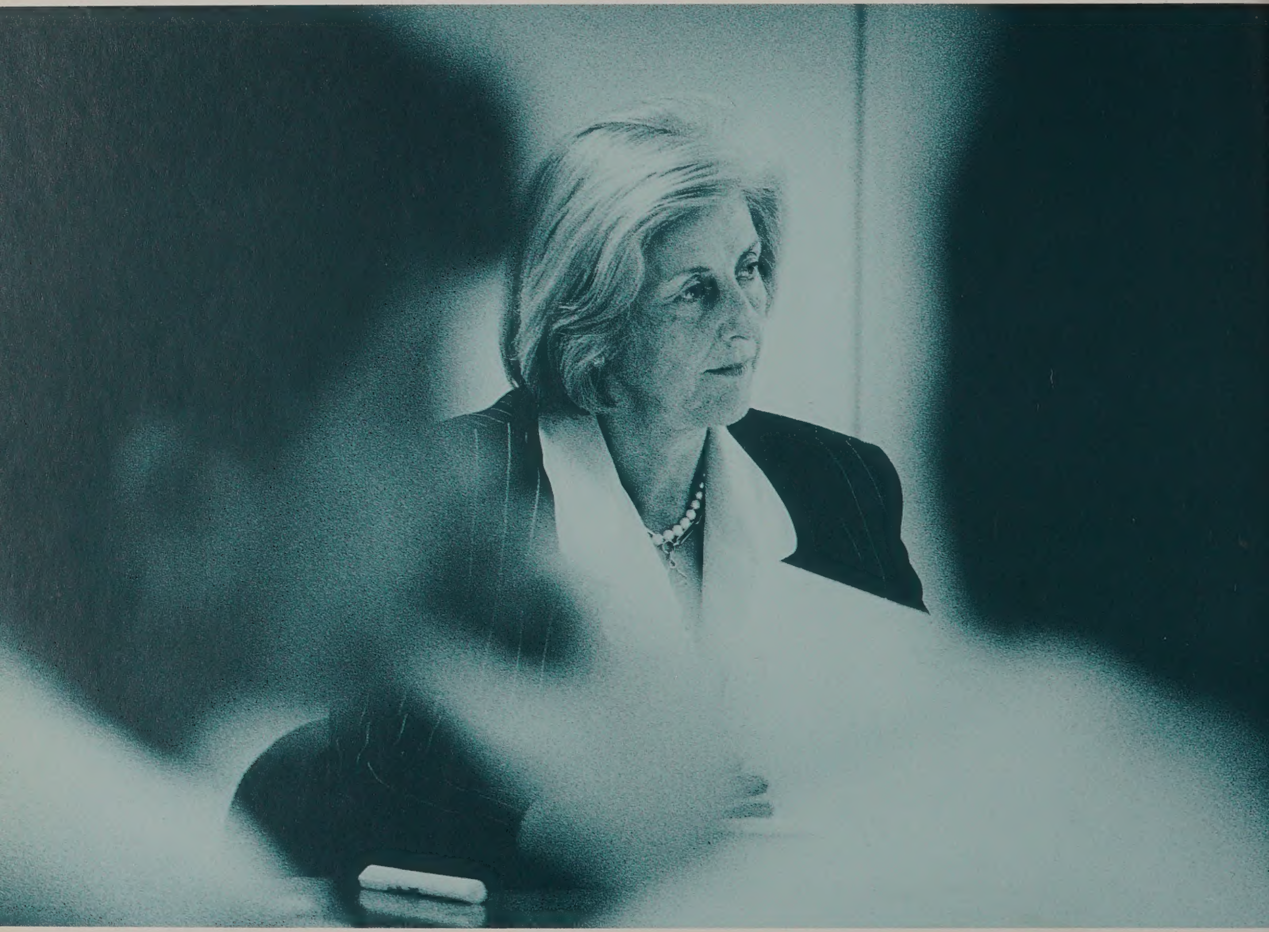
THE BACKGROUND AND HISTORY OF THE HFEA

The events that led to the setting up of the Human Fertilisation and Embryology Authority can be traced back to 1978 and the birth of the world's first 'test-tube' baby. Technological advances in assisted conception had raised important questions about their social and ethical implications, and the public and parliamentary debates which followed were well documented.

The notion of a statutory body to oversee the practice of certain advanced assisted conception techniques and of embryo research emerged with the publication in 1984 of the report of the Committee of Inquiry into Human Fertilisation and Embryology (the 'Warnock' report). After consultation and extensive debate in both Houses of Parliament, the Warnock Committee's proposals for such an Authority remained intact.



In 1985 the Medical Research Council and the Royal College of Obstetricians and Gynaecologists set up the Voluntary (later to become Interim) Licensing Authority for Human In Vitro Fertilisation and Embryology (ILA). It conducted an effective voluntary licensing system.

The passing of the Human Fertilisation and Embryology Act in 1990 meant that a statutory body was set up to oversee the area of assisted conception. It became the only national regulatory body in the world set up by statute to regulate fertility treatment. For the first time, an area of medicine, assisted reproduction, was to be controlled by an independent statutory body rather than by voluntary or self regulation.

The Human Fertilisation and Embryology Authority (HFEA) took up its full powers on 1 August 1991. It is an independent body, established by Parliament, and funded by income from its licensing of clinics and through a Government grant.

THE ROLE OF THE HFEA

The principal task of the HFEA is to license and monitor those clinics that carry out *in vitro* fertilisation (IVF), donor insemination (DI) and embryo research. The HFEA must ensure that treatment and research using human embryos are undertaken with the utmost respect and responsibility and that the vulnerability of infertile patients is not exploited. The HFEA also regulates the storage of gametes (sperm and eggs) and embryos.

In regulating treatment and research, the HFEA has to consider all relevant interests concerning patients, children and potential children, licensed clinics, the wider public and Parliament. It also needs to consider issues of safety, efficacy and ethics.

The HFEA's other main functions under the law are:

- *to keep a formal register of information about donors, treatments and children born from those treatments. This is so that children born as a result of donated eggs or sperm can find out, if they wish, something about their genetic history;*
- *to produce a Code of Practice which gives guidelines to clinics about the proper conduct of licensed activities;*
- *to publicise its role and provide relevant advice and information to patients and donors and to clinics;*
- *"to keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this [HFE] Act, and advise the Secretary of State, if he asks it to do so, about those matters".*[1]

The HFEA must ensure that treatment and research using human embryos are undertaken with the utmost respect and responsibility.

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[1] *Human Fertilisation and Embryology Act 1990, Section 8(a).*

3

THE MEMBERSHIP OF THE AUTHORITY

The HFEA comprises a Chairman, Deputy Chairman and 19 Members, appointed by the Secretary of State, who determine the policy of the Authority and licence applications. The Members bring to the Authority a broad range of medical, scientific, social, legal and religious knowledge and experience. It is a requirement of the Human Fertilisation and Embryology Act 1990 that the Chairman and Deputy Chairman and at least half of the HFEA Members are not doctors or scientists involved in research or practice relevant to infertility. A full list of the Members is contained in Annex 1, with committee and working group membership in Annex 2.

The HFEA Members are involved in official Authority business on average about three times a month. They attend the monthly meetings of the Authority, undertake inspections and sit on the Authority's licence committees and other standing committees and working groups.

THE EXECUTIVE AND COMMITTEE STRUCTURE

The HFEA's Executive comprises a Chief Executive, Deputy Chief Executive and 24 other staff who are responsible for implementing policy and licensing decisions of the Members and undertaking the day to day activity of the Authority. The Executive is divided into five sections which each report to particular HFEA committees and working groups. The sections are :

Policy and Ethics
reporting to the Code of Practice Committee and the Ethics Committee;

Resource Management
reporting to the Organisation and Finance Committee and the Audit Committee;

Communications
reporting to the Communications Steering Group;

Licensing
reporting to the Licensing and Fees Committee, licence committees and the Working Group on New Developments in Reproductive Technology; and

Data Management
reporting to the Information Committee.

The structure of the Executive is under regular review to ensure it best meets the needs of a small organisation and that it can respond quickly and flexibly to changing situations.

> *At least half of the HFEA Members are not doctors or scientists involved in research or practice relevant to infertility.*

Flora Goldhill
Chief Executive
(until July 1996)

Suzanne McCarthy
Chief Executive
(from July 1996)

Hugh Whittall
Deputy Chief Executive

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LICENCES ISSUED AND REFUSED

Each clinic in the UK which offers IVF or DI treatment, storage of gametes or embryos, or which carries out embryo research is required by law first to obtain a licence from the HFEA.

By definition, a newly licensed clinic will not, at the time the licence is issued following initial inspection, have carried out any licensable treatment. As with all clinics the Authority will monitor these clinics to ensure that their practice meets the standards required by the HFE Act and the Code of Practice.

There are currently 73 clinics licensed for IVF treatment (most of which also provide donor insemination), 38 for donor insemination only and 12 for the storage of sperm only. A list of currently licensed clinics is at Annex 3. There are 25 licensed research projects. A detailed report on research is provided in Section 6 of this report.

During 1995 12 new licences were issued, 5 for IVF, 5 for DI and 2 for sperm storage.

The 1994 Annual Report indicated that a licence committee proposed not to renew the licence of one IVF clinic and to revoke the licence of an associated clinic. The clinics made representations to a licence committee which upheld its earlier decision. The clinics subsequently appealed against the decision. The appeal, which takes the form of a re-hearing before the Authority, took place in

July 1995. The clinics and the licence committee were represented. The appeal committee upheld the non-renewal and revocation of the clinics' licences.

THE NEW LICENSING SYSTEM AND ITS DEVELOPMENT

The Authority normally inspects each licensed clinic every year. Under the licensing system in operation in 1995, both broadly based inspections and highly focused inspections were carried out as directed by the licence committees which offered the existing licences. Broadly based inspections are usually carried out by a team of four, one of whom would be an employee of the Authority and the three others with relevant experience in the provision of patient care. A Member of the Authority normally acts as chairman. A team for a highly focused inspection would include an Inspector(s) with the appropriate experience as specified by a licence committee, and an employee of the HFEA. Normally, the chairman of the inspection team would be a Member of the Authority.

The Authority has refined this system further by introducing a three year licensing cycle in which all clinics will receive one broad-based general inspection by a full team at least once every three years with highly focused inspections, as directed by licence committees, in the intervening years. Additionally a number of clinics will be the subject of an HFEA audit. Initially this will concentrate on the clinic's data, including the data which go into producing 'The Patients' Guide to DI and IVF Clinics', consent forms completed by patients and donors, and other administrative procedures.

THE HFEA PANEL OF INSPECTORS

The HFEA panel of Inspectors has remained largely unchanged since the Authority was set up. In late 1995, with the further development of the licensing system beginning to take shape, the Authority examined the skills and experience of the panel and decided that additional Inspectors were needed. In future, the majority of inspections will involve more focused consideration of specific aspects of a clinic's activities and this will require particular skills and depth of knowledge and experience on the part of the inspection team. It is therefore important to ensure that our Inspectors have the depth and range of experience required to enable the Authority to fulfil its statutory objectives in monitoring the activities of licensed clinics. The HFEA also requires objectivity on the part of its Inspectors as well as a full understanding of current Authority policies.

The majority of inspections will involve more focused consideration.

With this in mind, the Authority carried out a recruitment exercise with nominations for Inspectors being received from individuals and organisations together with self-proposal. Potential new HFEA Inspectors were asked to submit their curriculum vitae (CV) and indicate why they thought they were suitable to become Inspectors and the contribution they could make to the Authority's work. Existing Inspectors who were willing to continue also supplied their CVs and were asked for a statement on their view of the role of an Inspector. An Authority committee was set up to select the new panel of Inspectors.

The new group of Inspectors (see Annex 5) are a mixture of experienced and new Inspectors.

LICENSING OF ICSI

ICSI (Intra Cytoplasmic Sperm Injection) is a relatively new IVF technique where a single sperm is injected into the cytoplasm of an egg (oocyte) using a very fine glass needle. ICSI can be of particular value for male infertility. The skills and experience of the ICSI practitioner are key factors in the successful application of the technique.

Initially clinics had gained ICSI licences following licensed research on the technique or experience gained abroad. The Authority

The Authority monitors the performance of all ICSI practitioners.

recognised that demand for the use of the technique would grow, that opportunities for research would continue to decline and that the licensing of ICSI would require a more standardised system.

The issue was considered by the Authority's Working Group on New Developments in Reproductive Technology.

Under the new system, a clinic applying for a licence to practice ICSI has to provide both clinic and practitioner-oriented information. The former consists of the clinic's patient selection criteria for ICSI treatment, information for patients about ICSI, consent forms for ICSI treatment and laboratory protocols and procedures for ICSI. The practitioner information depends upon whether the embryologist has already been recognised by the Authority as competent to carry out clinical ICSI. If they have, their record of ICSI practice over the past year is required. Where the individual has not so far been recognised, their CV and training record are required together with a report from an HFEA Inspector (skilled in ICSI) on their suitability to carry out clinical ICSI based on an on-site examination of their practical skills. This information is considered by a licence committee.

The Authority monitors the performance of all ICSI practitioners on an annual basis with new practitioners being monitored three months after commencing clinical ICSI.

ENFORCEMENT POWERS

The Authority has investigated a number of alleged or apparent breaches of the HFE Act, or the Authority's Directions or Code of Practice. The first step involves preliminary enquiries to determine whether there is *prima facie* evidence of a breach. If there is such evidence, then the facts and circumstances are investigated. Specialist advice, including legal advice, is sought where necessary.

Information will then be submitted to a licence committee which will decide what further action, if any, needs to be taken.

Where there is the possibility that a criminal offence has been committed under the HFE Act the committee will decide whether the police should be involved, and whether the matter should be referred to the Director of Public Prosecutions.

Licence committees insist on the maintenance of the proper standards in treatment and research and a breach of the HFE Act, or Directions or the Code of Practice, could result in a licence being revoked or suspended.

Normally, concerns about a clinic arise from an inspection or from complaints by patients. They may also come from the clinic itself admitting that it has a problem or that it has made an error. It is also possible that a member of a clinic's staff may raise concerns. All these routes lead to enquiries being made and papers being placed before licence committees if the concerns raised indicate

(a) that there has been a breach of the Act, of the Code of Practice or of the Authority's Directions to clinics; or

(b) that a patient was improperly treated by a clinic or that improper procedures or practices were used; or

(c) that patients complaints are not dealt with properly.

In considering such matters, a licence committee will review a clinic's licence taking account of all the information before it and of all the circumstances. In determining the outcome, a licence committee has the power to: revoke a licence, not renew a licence, suspend a licence, and add conditions to a licence. It also has the power to require a change in the person responsible under whose supervision the activities in the clinic are carried out.

In regulating clinics, the Authority's aim is primarily to raise standards and licences are revoked or not renewed as an exception. Such an exception might be any case in which there were serious or persistent breaches and where the licence committee did not consider the clinic likely to improve sufficiently within a reasonable period of time. This has not been the case for any clinic in the past year.

As mentioned above, another action open to a licence committee is the suspension of a licence where the committee "has reasonable grounds to suspect that there are grounds for revoking the licence under section 18 of this [HFE] Act, and is of the opinion that the licence should be immediately suspended"[2]. Any clinic whose licence was suspended would no longer be able to provide treatment and therefore such an action would be taken only in extreme cases where it was necessary to protect patients. So far, this option has not been required by any licence committee.

Some clinics have received short licences (ie less than the standard one year) to demonstrate the extent of a licence committee's concern and to put clear pressure on the clinic to comply within a short period of time. Unless the licence committee's concern is resolved satisfactorily, the licence is unlikely to be renewed. Six short licences were issued in the past year.

In addition, a number of licences have had conditions attached to them which have limited the activities of the clinic concerned until a particular problem has been dealt with. This is the option most commonly used by licence committees in dealing with breaches or concerns and 83 licences were issued in the past year with additional conditions.

[2] *HFE Act 1990, section 22 (1(a)).*

Any improper treatment or procedures by clinics are taken very seriously indeed by the Authority.

The conditions relate mainly to matters in the Code of Practice and cover issues ranging from the need to amend patient information to a requirement to change the personnel involved in the provision of treatment services. The effect is to signal to the clinic that an issue must be addressed, and it also gives a signal that failure to comply might result in further, more drastic action being taken. For example, the licence committee might require a change in the "person responsible", ie the person under whose supervision the licensed activities are carried out. This happened on one occasion in the last year.

There should be no doubt, therefore, that breaches and any improper treatment or procedures by clinics are taken very seriously indeed by the Authority.

TRANSPORT IVF

Transport IVF is a procedure in which egg recovery and patient preparation takes place at a hospital or clinic which is not licensed by the HFEA. (This is permissible because neither activity of itself is licensable.) The eggs are then transported to the licensed clinic and mixed with sperm to create embryos. The subsequent embryo transfer takes place at the licensed clinic. It has always been the task of the licensed clinic to ensure that the requirements of the HFE Act and Code of Practice are met by the satellite clinic. These include the provision of patient information, the availability of counselling, protocols for taking account of the welfare of the child and confidentiality of information about patients and donors.

In the new Code of Practice the definition of transport IVF has been revised to cover any part of treatment services that take place in a unit not covered by a licence (eg the availability of counselling and the need to take account of the welfare of the child before treatment is offered).

This wider definition of transport IVF, which was introduced to protect patients by ensuring that all aspects of treatment are regulated under all circumstances, may have considerable implications for licensing. The Authority has embarked on a project to determine the degree to which the changes will impact upon the number of unlicensed clinics involved in carrying out transport IVF with licensed clinics and the operational arrangements between the two sets of clinics.

The Royal College of Nursing last year set up a working group on transport IVF. The group formulated guidelines for nurses working in units offering transport IVF. A copy of the guidelines has been incorporated into the manual which the HFEA has issued to all its Inspectors.

SPERMATIDS

In 1995 a clinic reported the use of spermatids (immature sperm) in an ICSI procedure. This is a novel procedure on which the Authority has ruled that further research is required. The clinic was told, therefore, that it should not carry out further treatments until the Authority had seen more information about the technique and approved its use. There is some human embryo research taking place in the UK regarding this procedure and the Authority will review the findings of this research and may allow treatment using spermatids when it is satisfied about the safety of the procedure.

This technique, which has also been used in France, has the potential to help a number of men with severe fertility problems to conceive children who are genetically their own when they could not otherwise do so.

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From the outset, one of the HFEA's aims in implementing the law has been to set proper standards for clinics and produce guidelines which are practicable for them to follow. The HFEA must by law produce a Code of Practice to guide clinics on how they should carry out licensed activities. All licensed clinics and research centres are expected to follow the professional, legal and ethical standards set out in the Code which provides part of the framework for the Authority's monitoring activities.

The Code is reviewed regularly. It is updated in the light of advances in techniques to deal with issues which emerge from the licensing process. The first revision was published in June 1993 and the second revision was published in December 1995. Revisions of the Code must be approved by the Secretary of State and laid before Parliament. Copies of the Code are available from the HFEA free upon request.

SECOND REVISION

The second revision of the Code of Practice is the current edition and it incorporates the policy decisions which the Authority had made and notified to licensed clinics since 1993 when the first revision was completed. These include HFEA policy to allow sex selection of children for medical reasons only in licensed clinics and the policy not to permit cloning by artificially splitting early embryos

Screening gamete donors for cystic fibrosis has become an increasingly common practice.

The current edition also explains the requirements of the law on Access to Health Records, and the Parental Orders Regulations 1994. Parental Orders provide a procedure for transferring legal responsibility for a child from birth parents to commissioning parents in surrogacy cases, where one or both of the commissioning parents is genetically related to the child.

The second revision of the Code contains clarification or further advice on a number of policy issues. These include: factors to take into account when considering, before offering treatment, the welfare of any child who might be born; the consent required for use and storage of gametes and embryos; responsibility for controlling the number of offspring from a donor; and guidelines in cases where material is stored for cancer patients.

THIRD REVISION

The Code of Practice is kept under constant review and the process of revising the Code for a third time has already started. Two issues that are being considered for inclusion in the next revision had already been identified when the second revision was published: the upper age limit for sperm donors and the screening of gamete donors for cystic fibrosis. Licensed clinics have been consulted on these issues and the Authority will take their responses into account, along with others received, before making its final decisions. The Code will also provide guidance on a number of issues, including those outlined below.

Upper age limit for sperm donors

The Code of Practice states that gametes should not be taken from male donors over the age of 55, unless there are exceptional reasons for doing so. The Authority has decided to review the evidence that is available on the genetic effects of paternal age. In particular, there is some evidence that suggests that the incidence of serious non-chromosomal birth defects, especially those arising from new autosomal mutations, increases with paternal age.

The responses received from licensed clinics and other interested organisations have shown that the Authority will have to consider the following points:

- the reliability of the evidence available;
- the effect of a lower age limit on the supply of donors;
- the level of risk to which it is acceptable for patients using donated gametes to be exposed; and
- whether the data held by the HFEA's information register should be included in the assessment.

Screening gamete donors for cystic fibrosis

Cystic fibrosis is the most common autosomal recessive condition in northern Europeans, and screening gamete donors for cystic fibrosis has become an increasingly common practice at licensed clinics. At present, the Code of Practice does not make screening for cystic fibrosis mandatory.

Responses that have been received by the Authority so far indicate a number of issues that will need to be addressed. For example, patients will need to have as much information as possible about the screening that donors have undergone. Patients should be aware of the risks involved and it has been suggested that patients should have the option of being screened for cystic fibrosis if the donors at their clinic are not routinely screened. The importance of choice is emphasised by the availability of cystic fibrosis screening in antenatal clinics.

Concerns about making screening of donors mandatory include:

- the cost of screening, which would inevitably be passed on to patients;
- the limitations of a test that only detects 85% of carriers; and
- the variation in the distribution of genetic disorders in different population groups even across the UK.

Screening for cystic fibrosis also raises wider issues about genetic screening which make it a complex area. For example, should other genetic disorders be screened for when tests become available; or is it possible to agree a level of risk to patients that is acceptable?

These are particularly pertinent questions in respect of those patients who have donor insemination in order to avoid transmitting a genetic disorder that has already been identified from their family history.

The availability of genetic counselling for patients and donors who are screened and the implications for clinics of dealing with genetic information are also issues that will need to be considered. The Authority has sought the views of the British Andrology Society on screening for cystic fibrosis.

Treatment of HIV positive patients

Following the well publicised IVF treatment of an HIV positive woman, the issues surrounding the treatment of HIV positive patients have been recently debated. The Authority will be considering whether any additional guidelines are required on welfare of the child issues for such cases where there may be particular risks involved. The Authority has decided to widen its consideration of the issues to include any potentially life-threatening disease or disorder that may be transmitted to the potential child or may cause the premature death of one or both of that child's parents. It is important that these issues are reviewed by the Authority regularly.

Regulations affecting the statutory storage period for embryos

The new Code of Practice will include guidance on the changes to the legislation governing the statutory storage period for embryos. The Human Fertilisation and Embryology Act 1990 determined that the maximum storage period for embryos should be five years. This took effect from 1 August 1991 and, for all embryos in storage at that date, the five year period ends on 31 July 1996.

The HFE Act did however contain a regulation – making power to change the storage period in certain circumstances. Regulations were made by Parliament and came into force on 1 May 1996 . These regulations allow the storage period to be extended to ten years if the people who provided the sperm and eggs which produced the embryos give their written consent to a longer period and if specific conditions are met. In certain specific circumstances some patients will be able to store embryos until the woman reaches the age of 55.

Regulations allow the storage period to be extended to ten years if specific conditions are met.

The Authority issued detailed guidance to all clinics explaining these changes before the regulations came into effect (1 May 1996). The HFEA also produced information leaflets for patients on the storage of embryos and on consent. Over the past year, the Authority has been in close contact with licensed clinics to ensure that all reasonable steps have been taken to contact patients and keep them informed. Patients can then decide whether or not they wish to extend the storage period for embryos which are coming to the end of the normal five year storage period. Clinics must obtain consents from the people who provided the eggs and sperm which produced the embryos, including any donors. If, for any reason, a clinic has not been able to obtain these consents, the embryos cannot remain in storage past five years and, by law, must be allowed to perish.

It has been suggested that the consent of the patients should be obtained before embryos are allowed to perish in such circumstances. The Authority believes that it is highly desirable for the people who provide the gametes to be fully involved at all stages in reaching decisions about what should happen to the embryos. However, if they cannot be contacted or are unwilling to make a decision, the embryos could stay in storage forever. This would clearly not be acceptable. The requirement for specific written consent to storage and use and the limit on the storage period for embryos means that decisions about what to do with those in storage cannot be put off indefinitely.

The requirement for specific written consent from individuals to the storage and/or use of their gametes is an important tenet of the HFEA Act. Since 1991 the law has required that people providing eggs or sperm must be given relevant information and offered counselling before consenting to the storage and use of gametes or embryos. In giving their consent, they must state what should be done with the embryos in the event of their death or mental incapacitation. They can also contact the clinic at any time to discuss the question of the embryos in storage and vary the terms of their consent up to the point at which the embryos are used.

Directions on payment of egg donors

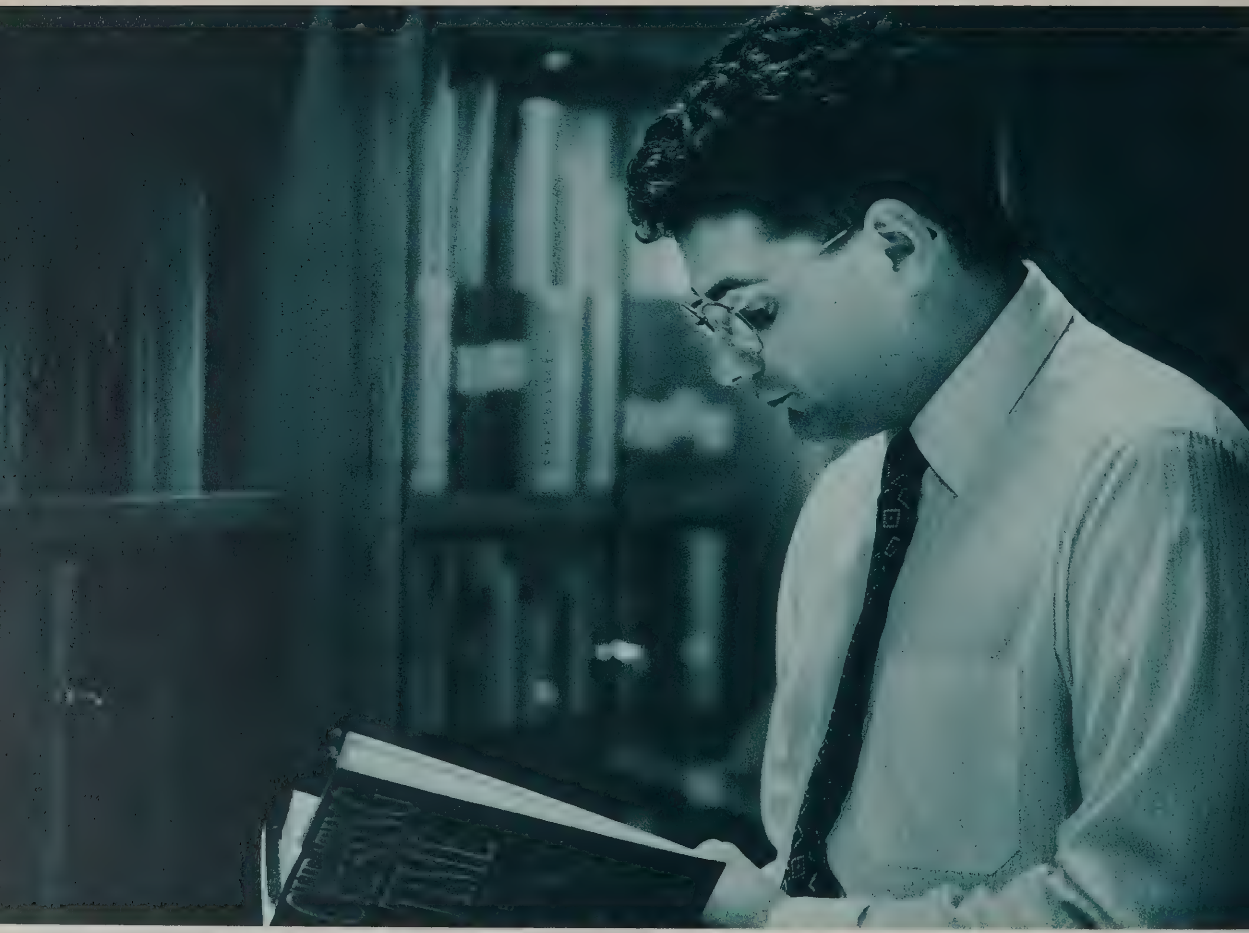
The Authority issued Directions in 1991 concerning the payment of egg and sperm donors. These Directions stated that clinics could pay donors up to £15 per donation plus reasonable expenses or offer free treatment or sterilisation.

In February 1996, the Directions were amended to cover payments from third parties, agencies or intermediaries, limiting these in the same way as payment by clinics. Clinics are now prohibited from using donors whom they know to have been paid by a third party more than is allowed in the Directions. The Authority also issued guidance with the new Directions on the questions clinics should ask in order to satisfy themselves that a donor has not received an excessive amount of money or other benefits in kind from an intermediary.

6

INTRODUCTION

Any research project which involves the creation, keeping or use of human embryos outside the body must be licensed by the HFEA. For a research licence to be granted, the Authority must be satisfied that the use of human embryos is "necessary or desirable"[3] for at least one of the following purposes:



1. to promote advances in the treatment of infertility;
2. to increase knowledge about the causes of congenital disease;
3. to increase knowledge about the causes of miscarriages;
4. to develop more effective techniques of contraception; or
5. to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

The following activities involving human embryos are not permitted in the UK:

1. keeping or using an embryo after the appearance of the primitive streak or after 14 days, whichever is the earlier;
2. placing a human embryo in an animal;

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[3] *HFE Act 1990, schedule 2 (3)(2).*

3. replacing a nucleus of a cell of an embryo with a nucleus taken from the cell of another person, another embryo, or subsequent development of an embryo;
4. altering the genetic structure of any cell while it forms part of an embryo; and
5. using embryos for any other purposes except in pursuance of a licence.

LICENSED RESEARCH PROJECTS – AN UPDATE

Currently, the Authority has 25 licensed research projects (see Annex 4) at 16 different research centres, compared to 21 research projects licensed last year. Of the 25 currently licensed research projects, 13 have been licensed for the first time in the last year and 12 were licensed as ongoing projects.

Areas of current research which will or may result in the creation of embryos include:

- studies involving the cryopreservation of eggs (UMDS of Guy's and St Thomas' and MRC EETU St George's - London), or investigations into the control of sperm function (Edinburgh Royal Infirmary) ;
- studies on embryos concerning their biochemistry and ability to implant (University of York and Royal Victoria Infirmary, Newcastle-upon-Tyne);
- the application of Preimplantation Genetic Diagnosis (Hammersmith, London and Leeds General Infirmary) for medical purposes; and
- improving infertility treatments (Walsgrave Hospital and Oxford IVF Unit), and ICSI (King's College, London and NURTURE, Nottingham).

CHANGES TO THE PROCESS OF ISSUING RESEARCH LICENCES

Proposals for research projects involving the use of embryos have to be submitted for peer review to appropriate academic referees chosen by the Authority. In a recent review of licensing research projects, the Authority has taken steps in the last year to improve the efficiency of this system. This has included revision of the application forms for a research licence and changes to peer review forms and their guidance notes. In addition, the Authority has accepted the need for some research projects to be licensed for longer than the previous maximum period of one year. Therefore, in some cases, the duration of a research licence has been increased up to three years with annual inspections and progress reports required for licence committees as normal. In the next year, the Authority will continue to seek ways to improve the efficiency of the research licensing system.

Proposals for research projects involving the use of embryos have to be submitted for peer review.

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The Authority considers a number of ethical issues every year. Some of the most recent issues considered are briefly described below.

PREIMPLANTATION GENETIC DIAGNOSIS

The Ethics Committee is currently considering preimplantation genetic diagnosis. It is a fairly new technique whose implications need to be explored further.

Researchers are increasingly able to identify the genes responsible for a variety of different conditions.

Preimplantation genetic diagnosis is used to detect whether an embryo created *in vitro* is carrying a genetic defect which will give rise to a serious inherited genetic disorder. It can also be used to determine the sex of an embryo in cases where a family is at risk of passing on a serious sex-linked disorder, such as Duchenne's muscular dystrophy to a male child.

The technique has been carried out at the Hammersmith Hospital for a number of years, mainly for cystic fibrosis, muscular dystrophy and a few other serious single gene defects. Elsewhere, several clinics have been carrying out research into preimplantation genetic diagnosis with a view to establishing clinical practice.

Researchers are increasingly able to identify the genes responsible for a variety of different conditions, which develop at different stages in life, for example, breast cancer or Huntington's chorea. There is therefore a likelihood that demand for preimplantation genetic diagnosis will increase as it becomes possible to detect which embryos are affected when there is a family history of such a disorder. The question for the Authority is how far it should go in licensing this technique for use in such cases.

The Authority's Ethics Committee has begun to examine the issues surrounding this complex subject. It has taken advice and evidence from a number of people with an interest in the field, including scientists, philosophers and groups representing those affected by genetic disorders. In May it hosted a meeting to begin to establish what criteria can be used in deciding what applications of preimplantation genetic diagnosis should or should not, on a moral basis, be allowed.

The Committee expects to report to the Authority before the end of 1996.

PAYMENTS TO GAMETE DONORS

The HFE Act states that no payment may be made for gametes or embryos except in accordance with HFEA Directions. When the HFEA took up its powers in August 1991, it issued Directions allowing donors to be paid up to £15 per donation plus reasonable expenses. The Directions also allow donors to receive free treatment services or sterilisation in exchange for donating gametes. Free treatment services or sterilisation are referred to as benefits in kind.

The Directions were intended to maintain and regularise the practice that existed when the HFEA took up its regulatory powers in 1991 in the interests of ensuring as smooth a transition for clinics as possible. The HFEA also wished to assess the impact of the new legislation more generally on the supply of gamete donors and to review the social and ethical issues surrounding the payment of donors.

In 1993, the HFEA therefore commissioned a survey into the motivations and attitudes of sperm donors. Male donors reported that both a wish to help others and the payment offered influenced their decision to donate. Donors and non-donors were also asked about personal and social aspects of donating sperm. For donors, the most common concern was that they would be contacted by offspring or that changes in the law would result in offspring being able to identify them. The women who were surveyed were almost all motivated by a wish to help others rather than payment. They were more concerned than their male counterparts about the possible existence of children they would never know.

Once the report of the survey of donors had been received in 1994, the HFEA began the process of review by setting up a working group of Authority Members. The working group reported its findings to the Authority in November 1994 and a conference on payment for donors was held in June 1995 to allow a wider consideration of the issues. The HFEA's 1995 Annual Report gave details of the conference and since then the Authority has continued to examine various aspects of payment for donors and has reached the following conclusions.

The Authority agreed that any policy should conform with three major principles in respect of gamete donation. These are that:

- the potential of gametes for producing human human life is worthy of respect;
- donation should be something entered into freely and voluntarily; and
- it should be a fully-informed decision.

The Authority considered whether payment for donors could in any way harm these principles. The Authority agreed that any risk that the decision to donate might be influenced by financial inducement was not desirable. In addition it was agreed that paying donors on the basis of the physical risks or discomfort undergone in making a donation was not acceptable. The Authority concluded that a donation should be a gift, freely and voluntarily given. However, it also concluded that donors should not be out of pocket as a result of becoming donors and that reasonable direct expenses, such as for travel and child care, could be reimbursed.

The Authority is aware of some interesting and worthwhile research involving donors currently underway.

Having reached these broad conclusions, the Authority does not wish to see the supply of donors diminish. A working group of Members has begun to examine how to implement the policy in detail and it will report back to the Authority. The working group is expected to present its recommendations to the Authority early in 1997.

The Authority is aware of some interesting and worthwhile research involving donors that is currently underway. It will take the results of all available research into account in considering how its policy might best be implemented so as to minimise any adverse effects on the number of donors coming forward. The Authority also welcomes the initiative taking place under the auspices of the Royal College of Nursing in which a number of interested organisations are considering ways of raising awareness of the need for unpaid donors.

SAFE CRYOPRESERVATION OF SPERM AND EMBRYOS

The Authority's 1995 Annual Report stated that a working group had been established to draw up guidance on the safe cryopreservation of sperm and embryos. This followed an incident involving the storage of bone marrow in which Hepatitis B had been transmitted. The Authority wished to consider if there were any lessons to be learned for the storage of gametes

The working group has prepared a draft report which the Authority will consider. This will also need to take account of the outcome of a Department of Health consultation exercise on the use of cryopreservation for the storage of other human tissue.

The Authority hopes to be able to issue guidance shortly.

HFEA PUBLICATIONS

Section 8(b) of the HFE Act requires the HFEA to "publicise the services provided to the public by the Authority or provided in pursuance of licences". In fulfilling this function, the HFEA offers a comprehensive range of information (see Annex 8).

This year the HFEA has taken over responsibility for the leaflet on donor insemination previously published by the Royal College of Obstetricians and Gynaecologists. It is planning to publish other information leaflets, for example, for oncology patients, in the coming year.

NATIONAL AND INTERNATIONAL COMMUNICATIONS

The HFEA receives thousands of requests every year from patients, the press and the public for information about fertility treatment and about the work of the Authority. Though most of these requests come from within the UK, they include many people who write to or phone the HFEA from abroad. As the UK is the only country in the world with a national regulatory body set up to control and monitor the area of assisted reproduction, advice and information about the British system is in frequent demand. This past year, the HFEA has supplied speakers at a number of national and international conferences to speak about regulation here in the UK. The HFEA's regular mailing list consists of over 250 British organisations and individuals interested in the work of the Authority and over 70 from overseas.

THE PATIENTS' GUIDE TO DI AND IVF CLINICS

For the first time last year, the HFEA produced a document which presented comparative statistical information about each of the clinics it licenses. This comprehensive Guide includes general information about DI and IVF treatments as well as specific information about each clinic.

The HFEA receives thousands of requests for information each year, the majority of these concerning information on choosing a clinic, and it believes that the Guide is beneficial to people about to undergo licensed fertility treatment.

The first edition of the Guide was published in October of last year. Since then, the HFEA has consulted again with patients, patients' groups and clinics regarding the Guide. The second edition, published in July 1996, has been redesigned to make it more comprehensible and to provide better information. It also includes some additional information for each clinic about frozen embryo cycles, donated egg and embryo cycles, the number of IVF cycles where two embryos were transferred, and singleton, twin and triplet births.

THE HFEA ANNUAL CONFERENCE

The HFEA holds an annual conference to provide an important platform for informed discussion and debate in the field of regulated fertility treatment. The one-day conference gives the staff of licensed clinics, the HFEA's Members, its Executive staff, its Inspectors and other delegates an unique opportunity to discuss issues of mutual interest and to exchange views and ideas.

The fifth HFEA Annual Conference was held in November 1995. Over 200 delegates attended. A number of subjects were addressed which centred around four themes: the statutory storage period for embryos, preimplantation genetic diagnosis, follow-up studies and the Patients' Guide. The speakers at the conference came from licensed clinics, from patients' support groups, from the Authority and from academic institutions. It was very useful for the Authority to hear the views expressed.

It was very useful for the Authority to hear the views expressed.

REVIEW OF LITERATURE ON EMBRYO FREEZING

In the 1994 Annual Report, the HFEA reported the findings of the Working Group on Embryo Freezing (WGEF). One of the tasks of this group was to investigate the implications that embryo freezing has for patients. The WGEF reported that "no evidence was found of lack of safety for patients or their potential children in the use of frozen embryos in treatment"[4]. The WGEF's report included a bibliography of scientific literature on embryo freezing from 1985-93.

The Authority considers it very important to keep the outcome of new developments, including embryo freezing, under review. Earlier in the year, therefore, the HFEA commissioned an updated review of the literature on the freezing of animal and human embryos. This project was undertaken by Dr Maureen Wood, the Senior Scientific Officer at the MRC Experimental Embryology & Teratology Unit in London and an HFEA Inspector. Her review confirmed the WGEF's earlier findings that there is no evidence that embryo freezing is harmful to patients or potential children. Dr Wood did promote the view, as the WGEF had done previously, that there is a need for more follow-up studies.

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[4] *HFEA Annual Report, 1994, p14.*

The HFEA hopes that Dr Wood will be able to publish her findings at a suitable opportunity.

THE CODE OF PRACTICE ON ENFORCEMENT

The HFEA's Code of Practice on Enforcement sets out the level of service that licensed clinics and the public can expect from the Authority. The HFEA adheres to the prinicple that the clinics and the public should have easy access to clear guidance about the Authority's regulations and that they should be able to complain without fear if they are unhappy with the way a regulation has been enforced.

Complaints

There are appointed persons within the HFEA's Executive who are responsible for dealing with complaints from clinics, patients and from members of the public. The Code of Practice on Enforcement is sent to the clinics and to Parliament and is available free of charge on request.

One formal complaint has been made about the Authority in the last ten months.

The Authority reviews annually its effectiveness in handling complaints and undertakes to make any changes that are necessary. There are separate statutory procedures for appeals against licence committee decisions.

Licensing

The Code of Practice on Enforcement informed clinics that the Authority expects to deal with applications, including inspections, within three months from receipt of the appropriate papers. The Authority found that seeking to achieve this target in three months was placing a greater burden on clinics, staff and Inspectors than was warranted. For it to be achieved, clinics could not be late with submitting their papers and there could be no flexibility for clinics' staff or Inspectors, in fixing the dates for inspections. The difficulties involved led to a number of clinics requiring short extensions to their licences and this was creating more work for HFEA staff and licence committees.

During the year, therefore, the Authority decided to allow four months for processing a licence renewal application, although achieving this is still dependent on clinics submitting papers in good time and it requires long-term planning to ensure that inspections are arranged for mutually agreed dates. The revised target provides a reasonable balance between the need for flexibility in the licensing process and the need to ensure that licence committees have information that is as up-to-date as possible when considering a licence renewal application, without any adverse effect on clinics.

New licence applications will continue to be processed in three months.

The Authority received over 1,200 requests for information over a period of about a week.

Information

The Authority receives on average 175 requests in a normal week for leaflets and forms from the general public and from clinics. On top of that, it is inundated with requests from members of the public when there is particular publicity given to one area which the Authority regulates. For example, when one television programme ran an item on sperm donation, the Authority received over 1200 requests for information over a period of about a week. Over 90% of requests are met within three working days.

Payments

The Authority paid all invoices where the invoice was correct within 28 days of receipt. On average, about 70% of all invoices are paid within 7 days and the remainder are paid within a month of receipt.

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As mentioned previously in this report, the following issues have been identified as future areas of discussion for the Authority:

Third revision of the code of practice

Assisted reproductive technology makes constant and rapid advances. As with any other field of science or medicine, good practice is regularly updated and new issues arise. It is for this reason that the Authority has always said that the Code of Practice would be subject to regular review and revision. As mentioned in Section 5, already a number of issues have been identified to be included in the next Code of Practice which the Authority hopes to send to clinics next Spring. These include:

- the use of agencies in the context of egg donation;
- the new statutory storage period regulations;
- screening for cystic fibrosis; and
- upper age limit for sperm donors.

Preimplantation genetic diagnosis

The Authority's Ethics Committee continues to examine preimplantation genetic diagnosis. This has been referred to in Section 7.

Report on safe cryopreservation

The Authority is planning to give further guidance to clinics later in the year on safe cryopreservation of gametes and embryos. This is also covered in Section 7.

Review of the level of fees

The level of fees charged for licences is clearly of great interest to clinics and to patients. The Authority tries to keep its costs – and therefore the fees it has to charge – to a minimum, though the actual level is determined through negotiations with the Department of Health and the Treasury. The Authority will be undertaking a review of fees later this year.

Implementation of the programme of auditing clinics

In addition to the new system of licensing (see Section 4), a programme of audit of the data supplied by clinics, in compliance with the Authority's Directions on the provision of information is being prepared whereby each clinic will be the subject of an HFEA audit every five years. Initially this will concentrate on the clinic's data returns to ensure that the data received are complete and correct.

What to do with patients' records when a clinic closes

There have been several occasions on which clinics have closed and questions have arisen as to how the confidential records should be kept secure while still being available for patients' future treatment. So far the records have been transferred to other licensed clinics because they have been willing to take on the responsibility of holding them securely and providing the patients concerned with appropriate access. However, the Authority needs to review the position and consider whether a formal procedure needs to be adopted and what role the Authority itself should play in determining how and where records from closed clinics should continue to be stored.

Guidelines for responding to requests for information

The Authority receives an increasing number of requests for information, derived from its database of IVF and DI treatments, each year from individuals, clinics, academics and Parliament. This demand cannot be met without taking account of the time and cost involved in providing the information, and the origin and control of the use of such information. The Authority is reviewing its procedures and will establish a formal mechanism for considering such requests.

The Code of Practice is subject to regular review and revision.

10

INTRODUCTION

The Authority has a statutory duty to collect information about licensed treatments and their outcomes in order to provide information to children born as a result of such treatments. To comply with this legal requirement the Authority maintains a register of information compiled from data provided by licensed treatment clinics. The data collected are also used to monitor the provision of IVF and DI at the clinics.

During 1995, the HFEA commissioned the upgrading of the database that holds the information about patients, donors, treatments and treatment outcomes. The new system is currently being developed and tested. Following an extensive parallel run with the current system, the new database is due to be fully implemented in early 1997. The new system will be more adaptable to the need to be able to collect information in response to new developments in treatment.

The HFEA has also introduced new forms on which IVF and DI treatment cycles and pregnancy outcomes are reported to the HFEA. The new forms were introduced into all treatment clinics on 1 April 1996 following consultation with clinicians and a pilot study. They allow much more detailed information to be collected, including new information on the male cause of infertility, the type of ovarian stimulation used and more detailed information regarding micromanipulation techniques such as ICSI.

The tables which follow have been compiled from data collected on the HFEA register for treatments carried out from 1 January to 31 December 1994 and their outcomes. During this period there were 69 clinics offering IVF treatment and 100 offering DI.

The number of pregnancies where no outcomes, or incomplete information, were reported to the Authority totalled 223 or 3.4% of all pregnancies.

IN VITRO FERTILISATION: 1 JANUARY – 31 DECEMBER 1994

The IVF data include treatments involving frozen embryo replacements and micromanipulation techniques, such as ICSI or SUZI, unless otherwise stated.

In 1994, 19,189 patients received IVF treatment. There were a total of 24,708 treatment cycles started, including frozen embryo replacements, of which 20,213 cycles reached embryo transfer. There were 4,417 clinical pregnancies reported which led to 3,477 live birth events.

TABLE 1
IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES: 1985-1994

Year	*Number of Treatment Cycles*	*Clinical Pregnancy Rate per treatment cycle (%)*	*Live Birth Rate per treatment cycle (%)*
1985	4308	11.2	8.6
1986	7043	9.9	8.6
1987	8899	12.5	10.1
1988	10489	12.9	9.1
1989	10413	15.4	11.1
1990	11583	17.3	12.5
1991	6653 *	17.8	13.9
1992	18224	16.9	12.7
1993	21823	18.0	14.2
1994	24708	17.9	14.1

* Data available for 1 August to 31 December only

This table records clinical pregnancy and live birth rates over a ten year period. The data prior to 1991 were collected by the Interim Licensing Authority (ILA) during which time the reporting of treatments and their outcomes was not compulsory.

The table shows that in 1994 there was an increase of nearly 3,000 IVF treatment cycles. The clinical pregnancy rate and live birth rate were 17.9% and 14.1% respectively. These data are not significantly different from that of previous years. The difference between the clinical pregnancy rate and live birth rate has also remained constant at around 4%.

TABLE 2
CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR FEMALE CAUSES OF INFERTILITY
(% are of number of treatment cycles)

Factor	*Number of Cycles*	*% of all Cycles*	*Clinical Pregnancy Rate (%)*	*Live Birth Rate (%)*
Tubal Disease	10640	43.0	16.7	12.9
Endometriosis	2569	10.4	18.3	15.0
Unexplained	9332	37.8	18.2	14.4
Other	4041	16.4	18.2	15.3

This table records infertility treatment resulting from a female factor. The largest group of treatments with a female indication recorded were due to tubal disease.

When the data in these tables have been adjusted to take account of the age of the woman and the duration of infertility, the difference between the clinical pregnancy and live birth rates for the different causes of infertility are not statistically significant.

The new data base is to be fully implemented in early 1997.

TABLE 3

IVF LIVE BIRTH RATES BY WOMEN'S AGE

Using own eggs

	Under 25	*25-29*	*30-34*	*35-39*	*40-44*	*45 and over*
Treatment Cycles	312	3729	9226	7842	2196	167
Live Birth Rate (% per treatment cycle)	17.3	17.2	16.0	12.3	5.4	2.4

Using donor eggs

	Under 25	*25-29*	*30-34*	*35-39*	*40-44*	*45 and over*
Treatment Cycles	12	112	195	250	243	171
Live Birth Rate (% per treatment cycle)	16.6	17.2	17.9	13.2	17.2	21.6

•This table excludes treatments using donated embryos

During this period, in 95% of all treatment cycles the woman's own eggs were used, in 4% donated eggs were used, and in 1% of treatments donated embryos were used. Of all treatment cycles, 42.1% were undertaken where women over 40 years old used donated eggs. By comparison, 10.1% of all cycles were undertaken where women over 40 used their own eggs.

The table shows that the live birth rate for women who use their own eggs decreases significantly from the age of 35, with the largest decrease being after the age of 39. The live birth rate for women using donated eggs remains relatively constant at around 17% for all ages. The apparent increase in the live birth rate after the age of 45 is not significantly different to the average live birth rate. Chance increases of this kind can occur because of the very low number of patients being treated.

This table excludes treatments using donated embryos.

TABLE 4

SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES AFTER IVF OR FROZEN EMBRYO TRANSFERS (all centres)

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Perinatal Deaths (per thousand births)*
Singleton	3064	2376	448	16	125	65	2380	14.1
Twin	1009	929	114	4	7	10	1747	58.3
Triplet	197	170	41	12	0	3	459	90.9
Quads	3	2	1	1	0	0	6	–
Totals	4273	3477	604	33	132	78	4592	29.7

NOTES TO ACCOMPANY TABLE

Twin and triplet pregnancies do not add up because a multiple pregnancy may have more than one outcome.

The number of babies born represents all the babies born for the type of pregnancies. For example babies born from twin pregnancies (two gestational sacs) will include birth events in which only one baby was born and babies born from singleton pregnancy (one gestational sac on an early scan) may include two babies.

The total number of clinical pregnancies shown here is less than the total given in other tables because there were 144 clinical pregnancies reported for which no outcome form was received.

The table includes 4 ectopic pregnancies in which no fetal sacs were recorded.

Table 4 indicates the numbers of single and multiple clinical pregnancies and their outcomes. The number of multiple clinical pregnancies has increased from the previous year to 28.3% of all IVF pregnancies compared to 26.2% in 1993. However, this increase is not statistically significant. The multiple birth rate was 31.7%

The table shows the number of perinatal deaths expressed as the number of deaths per 1,000 birth events in accordance with current convention. The incidence of perinatal death is significantly greater for higher order multiple births (triplets and quads). This reflects the complications associated with multiple pregnancy and birth, such as prematurity and low birth weight. The table also indicates that the miscarriage rate for triplets (20.8%) is significantly higher than for singletons (14.6%).

The number of clinical pregnancies that result in a termination includes pregnancies in which the number of embryos in the pregnancy has been reduced.

TABLE 5(a)

IVF SINGLETON AND MULTIPLE CLINICAL PREGNANCIES BY THE NUMBER OF EMBRYOS TRANSFERRED
(all centres; the data include frozen embryo transfers)

		No. of clinical pregnancies		
Embryos Transferred	*No. of cycles*	*Singleton*	*Twin*	*Triplet or greater*
One	2309	171	7	1
Two	6449	1001	288	8
Three	11455	1892	714	191*
Total	20213	3064	1009	200

TABLE 5(b)

IVF SINGLETON AND MULTIPLE CLINICAL PREGNANCY AND LIVE BIRTH RATES BY THE NUMBER OF EMBRYOS TRANSFERRED
(all centres; the data include frozen embryo transfers)

Embryos Transferred	*Clinical Pregnancy Rate (% of treatment cycles)*	*Live Birth Rate (% of treatment cycles)*	*Multiple Clinical Pregnancy Rate (% of clinical pregnancies)*	*Multiple Birth Rate (% of live births)*	*Perinatal Deaths (per thousand births)*
One	7.7	6.0	4.5	3.5	7.2
Two	20.1	16.4	22.8	21.8	25.1
Three	24.4	19.9	32.3	33.0	33.2

*Includes 3 sets of quads

The total number of clinical pregnancies is less than the total given in other tables because there were 144 clinical pregnancies reported for which no outcome form was received.

The above tables show the number of embryos transferred per treatment cycle. In 56.7% of all embryo transfers, three embryos were transferred. Two embryos were transferred in 31.9% of transfers and one embryo was transferred in 11.4% of transfers. The chance of a multiple clinical pregnancy and perinatal death does increase with the number of embryos transferred.

The data in the rows reporting cycles in which three embryos were transferred include three sets of quads. (These occurred as a result of embryo division when one of the one of the embryos in the pregnancy splits into two and gives rise to two fetuses.)

TABLE 6(a)

IVF CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR TWO AND THREE EMBRYO TRANSFERS (EXCLUDES FROZEN EMBRYO TRANSFERS)

(all percentages are of embryo transfers)

	Number of Transfers	*Number of Clinical Pregnancies*	*Clinical Pregnancy Rate*	*Live Births*	*Live Birth Rate*
Two embryos transferred where only two embryos were available	1549	227	14.7%	168	10.8%
Two embryos transferred where more than two embryos were available	3566	905	25.4%	736	20.6%
Three embryos transferred	9863	2630	26.7%	2059	20.9%

TABLE 6(b)

IVF SINGLE AND MULTIPLE PREGNANCY RATES FOR TWO AND THREE EMBRYO TRANSFERS (EXCLUDES FROZEN EMBRYO TRANSFERS)

(all percentages are of clinical pregnancies)

	Singletons	*Twins*	*Triplets*	*Quad*
Two embryos transferred where only two embryos were available	181(80%)	32(14%)	1 (0%)	–
Two embryos transferred where more than two embryos were available	653(72%)	231(26%)	7 (1%)	–
Three embryos transferred	1667(63%)	677(26%)	181 (7%)	3 (0.1%)

The above tables compare the differences in clinical pregnancy and live birth rates in cycles where two embryos were transferred and cycles where three embryos were transferred. Where two embryos were transferred, the results are split into those cycles where only two embryos were available for transfer and those where three or more were available. The first table shows higher than national average clinical pregnancy and live birth rates for patients who had more than two embryos available but who had only two embryos replaced, compared to those who had only two embryos available and both were replaced. The table also shows that the clinical pregnancy and live birth rate are comparable for both two and three embryo transfer when more than two embryos were available for transfer. This may reflect clinical practice in which patients with a good prognosis only have two embryos transferred. In cycles in which only two embryos were transferred, however, the second table shows that the multiple clinical pregnancy and multiple live birth rate are much reduced.

TABLE 7

TREATMENTS USING MICROMANIPULATION

Clinics	*Patients*	*No. of Cycles*	*No. of Embryo Transfers*	*Clinical Pregnancies*	*Clinical Pregnancy Rate (%)*	*Total Live Births*	*Live Birth Rate (%)*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown*	*Babies Born*	*Perinatal Deaths (per thousand births)*
22	1184	1356	1187	246	18.1	201	14.8	27	4	6	2	253	50.0

*1 clinical pregnancy with no outcome form received

This table represents the first publication of UK national data on IVF treatments involving micromanipulation. This includes techniques such as ICSI and SUZI.

The table shows that 1,356 treatment cycles were carried out during this period with a clinical pregnancy and live birth rate similar to the national average for all IVF treatments. A total of 253 babies were born as a result of these treatments. The rate of perinatal death is comparable to standard IVF procedures and the percentage of babies born with a congenital abnormality is less than that for other IVF and DI treatments (Annex 8).

DONOR INSEMINATION: 1 JANUARY – 31 DECEMBER 1994

All data in these tables include cycles involving GIFT and intrauterine insemination (IUI) using donor gametes.

There were 7,106 patients who received DI treatment during this period. A total of 21,180 treatment cycles were started which led to 2,059 clinical pregnancies and 1,671 live birth events.

TABLE 8
DI CLINICAL PREGNANCY & LIVE BIRTH RATES PER TREATMENT CYCLES: 1991-1994
(% are of number of treatment cycles)

Year	*Cycles*	*Clinical Pregnancy Rate (%)*	*Live Rate (%)*
1991	9262*	6.5	4.9
1992	26063	6.7	5.0
1993	24035	7.9	6.5
1994	21180	9.7	7.9

*Data available for 1 August to 31 December only

This is the second successive year in which the total number of DI treatments has declined. This may be partly due to the increased use of micromanipulation techniques, such as ICSI, to treat male infertility problems. The clinical pregnancy and live birth rates for DI treatments have significantly increased by just over 1%.

TABLE 9

DONOR INSEMINATION DATA (all centres)

	Stimulated DI	*Unstimulated DI*
Number of Centres	99	90
Number of Patients	3505	4591
Number of Treatment Cycles	8695	12485
Total Clinical Pregnancies	875	1184
Clinical Pregnancy Rate per Cycle	10.1%	9.5%
Total Miscarriages	102	131
Total Terminations	3	4
Total Ectopics	7	10
Total Live Births	707	964
Live Birth Rate per Cycle	8.1%	7.7%
Total Perinatal Deaths	8	5

The data in the two parts of this table are not directly comparable as it is often the case that a patient will commence treatment with unstimulated DI treatment and then switch to stimulated treatment. Stimulated treatment may also be of two types: the cycle may be stimulated in order that the ovaries produce more than one egg; alternatively, the stimulatory drugs may be used simply to regulate the monthly cycle.

The data show that 58.9% of DI cycles were unstimulated (ie one egg produced naturally during the menstrual cycle). The difference between the clinical pregnancy and live birth rates for stimulated and unstimulated DI are not great enough to be statistically significant.

TABLE 10

SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR STIMULATED DI (all centres)

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Perinatal Deaths (per thousand births)*
Singleton	727	601	98	3	7	12	602	9.9
Twin	93	90	3	0	0	2	177	11.1
Triplet	16	15	1	0	0	1	43	66.6
Quad	1	1	0	0	0	–	4	–
Totals	837	707	102	3	7	15	826	9.9

- 38 Clinical pregnancies recorded with no outcome form received

SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR UNSTIMULATED DI (all centres)

	Clinical Pregnancies	*Live Births*	*Miscarriages*	*Terminations*	*Ectopics*	*Unknown Outcomes*	*Babies Born*	*Perinatal Deaths (per thousand births)*
Singleton	111	948	129	4	10	15	948	5.3
Twin	17	15	2	0	0	1	28	–
Triplet	1	1	0	0	0	0	3	–
Totals	1129	964	131	4	10	16	979	5.2

- 55 Clinical pregnancies recorded with no outcome form received
- The total number of clinical pregnancies recorded is less than in other tables because 93 clinical pregnancies were reported with no outcome form received.

The above tables indicate that the incidence of multiple clinical pregnancy is higher for stimulated DI (13.1%) than for unstimulated DI (1.6%). The rate of perinatal death is also lower for unstimulated DI as there are fewer multiple births.

TABLE 11

DI LIVE BIRTH RATE BY WOMEN'S AGE

	Under 25	*25-29*	*30-34*	*35-39*	*40-44*	*45 and over*
Treatment Cycles	*905*	*5394*	*8485*	*4927*	*1391*	*78*
Live Birth Rate (% per treatment cycle)	*9.8*	*9.2*	*8.8*	*6.3*	*2.3*	*1.2*

Table 11 shows that the live birth rate for donor insemination decreases with the age of the woman. The same proportion of women aged 40 or over (6.9%) received treatment as did in the previous year.

11

THE HFEA BUDGET

The Authority's budget for the financial year 1995/96 was set at £1.36 million. The Authority is constantly mindful of the need to keep administrative costs to a minimum in order to limit licence fees and the burden on the taxpayer as far as possible. Although the number of clinics providing licensable treatment continues to grow, efficiency savings have been made by streamlining the licensing process. The Authority will continue to try to identify new areas where similar savings can be made without compromising the level of service that it provides.

LICENCE FEES

In July 1994, agreement was reached with the Department of Health and the Treasury about the amount of the Authority's expenditure to be funded from licence fees. In the year 1995/96, the Authority's financial objective was to raise 70% of its income from licence fees and this target was also set for 1996/97 and 1997/98. The fees charged to clinics in 1995/96 were £40 per IVF cycle and £10 per DI cycle and these fee levels continue to apply in 1996/97. The Authority will review the level of fees and the system for collecting fees in 1996/97. If there are to be any changes, clinics will be given as much notice as possible before they are to be introduced.

ANNEX 1

MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

CHAIRMAN
Ruth Deech
Principal
St Anne's College, Oxford

DEPUTY CHAIRMAN
Diana Brittan
Deputy Chairman,
Equal Opportunities
Commission;
Magistrate, City of London,
Chairman, Rathbone CI

MEMBERS

Professor Sam Berry
Professor of Genetics
University College London

Martin Johnson
Professor of Reproductive
Sciences, University of
Cambridge

Professor Rory Nicol
Professor of Child
Psychiatry, The Greenwood
Institute of Child Health,
University of Leceister

Jane Denton
Nursing Director,
Multiple Births Foundation,
Queen Charlottes &
Chelsea Hospital, London

Richard Jones
Legal Consultant

Professor Allan Templeton
Professor of Obstetrics
& Gynaecology,
University of Aberdeen

Liz Forgan
Former Managing Director
of BBC Radio

Penelope Keith
Actress

Professor the Reverend Canon Anthony Thiselton
Head of the Department of
Theology, The University
of Nottingham
Canon Theologian of
Leicester Cathedral

Mr David Greggains
Director
Gorham Partners Ltd

Dr Brian Lieberman
Medical Director, Regional
IVF and DI Unit,
St Mary's Hospital,
Manchester

John Williams
Dean, Faculty of Economic
and Social Studies,
University of Wales ,
Aberystwyth

Joan Harbison
Senior Lecturer in
Education, Stranmillis
College, Belfast

Angela Mays
Management Consultant

Julia Tugendhat
Family therapist

Professor Stephen Hillier
Professor of Reproductive
Endocrinology,
University of Edinburgh

Dr Anne McLaren
Principal Research
Associate,Wellcome CRC
Institute

Rabbi Julia Neuberger
(until November 1995)
Chairman, Camden &
Islington Community Health
Services NHS Trust

The Most Reverend Richard Holloway
Bishop of Edinburgh

Dr Jeanette Naish
General Practitioner, Senior
Lecturer, Department of
General Practice & Primary
Care, St Bartholomew's and
the Royal London School of
Medicine and Dentistry

David Shilson
(until November 1995)
Bank of England Agent,
Scotland

ANNEX 2

MEMBERSHIP OF HFEA COMMITTEES AND WORKING GROUPS

AUDIT COMMITTEE

Julia Tugendhat (Chairman)
David Greggains
Richard Jones
John Williams

CODE OF PRACTICE COMMITTEE

Robert Berry (Chairman)
Richard Holloway
Penelope Keith
Anne McLaren
Jeanette Naish
Rory Nicol
Allan Templeton

COMMUNICATIONS STEERING GROUP.

Diana Brittan (Chairman)
Liz Forgan
Joan Harbison
Penelope Keith
Brian Lieberman
Angela Mays
Anthony Thiselton

ETHICS COMMITTEE

Richard Holloway (Chairman)
Robert Berry
Liz Forgan
Joan Harbison
Anthony Thiselton
Julia Tugendhat
John Williams

INFORMATION COMMITTEE

Jeanette Naish (Chairman)
Jane Denton
Martin Johnson
Rory Nicol
Allan Templeton
Julia Tugendhat
John Williams
Co-opted members: Ian Cooke,
Joan Morris and Tony Rutherfold

LICENSING AND FEES COMMITTEE

Diana Brittan (Chairman)
Jane Denton
David Greggains
Stephen Hillier
Richard Jones
Brian Lieberman
Angela Mays

ORGANISATION AND FINANCE COMMITTEE

Ruth Deech (Chairman)
Robert Berry
Diana Brittan
David Greggains
Stephen Hillier

WORKING GROUP ON THE EFFECT OF REMOVING PAYMENT FROM DONORS

Martin Johnson (Chairman)
Jane Denton
Liz Forgan
Brian Lieberman
Angela Mays

WORKING GROUP ON NEW DEVELOPMENTS IN REPRODUCTIVE TECHNOLOGY

Anne McLaren (Chairman)
Jane Denton
Stephen Hillier
Martin Johnson
Richard Jones
Brian Lieberman
Alan Templeton
Observer: John Modle

ANNEX 3

LIST OF CLINICS CURRENTLY LICENSED BY THE HFEA FOR TREATMENT

Avon

Royal United Hospital, Bath
St Michael's Hospital, Bristol
Southmead General Hospital, Bristol
South West Regional Cytogenetics Centre, Bristol
University of Bristol IVF Service, The BUPA Hospital
Tower House Clinic, Bristol

Berkshire

Berkshire Independent Hospital, Reading
Orchid Centre, BUPA Dunedin Hospital, Reading

Buckinghamshire

BMI Chiltern Hospital, Great Missenden

Cambridgeshire

Bourn Hall Clinic, Cambridge
Rosie Maternity Hospital, Cambridge

Cleveland

Hartlepool General Hospital
South Cleveland Hospital, Middlesborough
North Tees General Hospital, Stockton-on-Tees
Cleveland Fertility Centre, Stokesley

Derbyshire

Derby City General Hospital

Devon

Royal Devon and Exeter Hospital, Exeter
Nuffield Hospital, Plymouth

Dorset

Winterbourne Hospital, Dorchester

East Sussex

Esperance Private Hospital, Eastbourne

Essex

Holly House Hospital, Buckhurst Hill
The BUPA Roding Hospital, Ilford
North East London Fertility Services, Ilford

Greater Manchester

Manchester Fertility Services, BUPA Manchester Hospital
St Mary's Hospital, Manchester
Withington Hospital, Manchester
Cromwell IVF and Fertility Centre, Hope Hospital, Salford
Billinge Hospital, Wigan

Hampshire

Basingstoke District Hospital
Hampshire Clinic, Basingstoke
BUPA Chalybeate Hospital, Southampton
Princess Anne Hospital, Southampton

Hertfordshire

Hertfordshire Fertility Services, Queen Elizabeth II Hospital
Watford General Hospital

Humberside

Princess Royal Hospital, Hull

Kent

Chaucer Hospital, Canterbury
BMI Chelsfield Park Hospital
Maidstone District General Hospital
Queen Mary's Hospital, Sidcup

Leicestershire

BUPA Hospital, Leicester
Leicester Royal Infirmary

London (Central)

BMI Portland Hospital
Bridge Fertility Centre, London Bridge Hospital
Chelsea & Westminster Hospital
Churchill Clinic
Cromwell Hospital
Dr Louis Hughes
Dr Katz, University College Hospital
Lister Hospital
London Gynaecology and Fertility Centre (2)
London Welbeck Hospital
London Womens' Clinic/Hallam Medical Centre (4)
Middlesex Hospital
Pregnancy Advisory Service
St Bartholomew's Hospital
St George's Hospital

Samaritan Hospital For Women
UMDS - St Thomas' Hospital
University College Hospital

London(East)

Homerton Hospital
Newham General Hospital

London (North)

Highgate Private Hospital

London (South)

King's College Hospital

London (West)

Royal Masonic Hospital
West Middlesex University Hospital
Wolfson Family Clinic,
Hammersmith Hospital

Merseyside

Fazakerley Hospital, Liverpool
Liverpool Women's Hospital
Rodney Fertility Clinic, Liverpool
BUPA Murrayfield Hospital, Wirral

Northern Ireland

Royal Maternity Hospital, Belfast

Norfolk

BUPA Hospital, Norwich

Northamptonshire

Three Shires Hospital, Cliftonville

Nottinghamshire

BMI Park Hospital, Arnold
Nottingham City Hospital
NURTURE, University of Nottingham
Queen's Medical Centre, Nottingham

Oxfordshire

Churchill Hospital, Oxford
John Radcliffe Hospital, Oxford

Scotland (Grampian)

Aberdeen Maternity Hospital

Scotland (Lothian)

Royal Infirmary of Edinburgh
Western General Hospital, Edinburgh

Scotland (Orkney)

Balfour Hospital, Orkney

Scotland (Strathclyde)

Monklands District General Hospital, Airdrie
BMI Ross Hall Hospital, Glasgow
Glasgow Nuffield Hospital
Glasgow Royal Infirmary

Scotland (Tayside)

Ninewells Hospital, Dundee

Shropshire

Royal Shrewsbury Hospital

Staffordshire

North Staffordshire Hospital, Stoke-on-Trent

Surrey

Shirley Oaks Hospital, Shirley
Woking Nuffield Hospital

Tyne and Wear

Royal Victoria Infirmary,
Newcastle-upon-Tyne
Sunderland District General Hospital
Cromwell IVF & Fertility Centre,
Washington Hospital

Wales (South Glamorgan)

University Hospital of Wales,Cardiff

Wales (West Glamorgan)

Neath General Hospital
Singleton Hospital, Swansea

West Midlands

Midland Fertility Services, Aldridge
Birmingham Maternity Hospital
BMI Priory Hospital, Birmingham
Walsgrave Hospital, Coventry

Yorkshire (South)

Doncaster Infertility Services
Jessop Hospital for Women, Sheffield
Sheffield Fertility Centre

Yorkshire (West)

Clarendon Wing, Leeds General Infirmary
St James' University Hospital, Leeds

Clinics with storage licences only

North West Wales Fertility Centre, Bangor

Royal Sussex County Hospital, Brighton
Cheltenham General Hospital

Danum Lodge Nursing Home, Doncaster

Royal Surrey County Hospital, Guildford
Blackdown Nursing Home, Leamington Spa

Bridge Fertility Services Donor Bank, London

Queen Charlotte's and Chelsea Hospital, London

The Walm Lane Clinic, London

Newcastle General Hospital, Newcastle-upon-Tyne

Nottingham City Hospital

Singleton Hospital, West Glamorgan

LIST OF CURRENT RESEARCH PROJECTS

BOURN HALL – CAMBRIDGE

Cytokines in reproduction*

ROYAL VICTORIA INFIRMARY NEWCASTLE-UPON-TYNE

A study of the role of intracellular calcium in the development of human preimplantation embryos*

EDINBURGH ROYAL INFIRMARY

ICSI studies on cellular events following sperm injection*

Cell biology of human spermatozoa

Culture of multipotential human embryos*

HAMMERSMITH HOSPITAL – LONDON

To measure the activity of metabolic enzymes in spare human preimplantation embryos

To measure the activity of enzymes implicated in genetic disorders

Preimplantation genetic diagnosis parallel investigations

HULL IVF UNIT

Investigations into a novel technique devised to overcome male immunological subfertility*

KING'S COLLEGE – LONDON

Investigation of the effects of co-culture with the endometrial cells on the viability of human preimplantation embryos

Cytogenetic analysis of human preimplantation embryos following ICSI*

LEEDS GENERAL INFIRMARY

Diagnosis of trisomies and DNA fingerprinting in human blastomeres to improve preimplantation genetic diagnosis*

MRC EETU ST GEORGE'S – LONDON

Cryopreservation of human oocytes

NURTURE – NOTTINGHAM

Evaluation and use of the hamster egg penetration test*

Evaluation of the use of spermatids for achieving conception *in vitro**

OXFORD IVF UNIT

The use of growth factors to improve human embryo culture for *in vitro* fertilisation*

ST BARTHOLOMEW'S HOSPITAL

Release of lymphokines by the human embryo

UMDS OF GUYS' AND ST. THOMAS'

Studies of methods for the cryopreservation of human oocytes*

Improving methods for the biopsy and diagnosis of inherited genetic disease of human preimplantation embryos

UNIVERSITY OF YORK

Biochemistry of early human embryos

WALSGRAVE HOSPITAL – COVENTRY

Use of co-cultures in human IVF

A two-part study of human sperm injected into human eggs*

UNIVERSITY OF WARWICK

Use of co-cultures in human IVF

A two-part study of human sperm injected into human eggs*

WITHINGTON HOSPITAL – MANCHESTER

In vitro development and implantation of normal human pre-embryos and comparisons with uni- or poly-nucleate pre-embryos

** Research projects licensed in the last year*

ANNEX 5

LIST OF CURRENT HFEA INSPECTORS

Dr Masoud Afnan
Consultant Gynaecologist & Obstetrician; Senior Lecturer, Director of Birmingham Maternity Hospital's Assisted Conception Unit

Dr Sue Avery
Prinicpal Scientist, Bourn Hall, Cambridge

Dr Linda Baggott
Lecturer in Biology and Education, University of Exeter

Professor David Barlow
Nuffield Professor of Obstetrics & Gynaecology, John Radcliffe Maternity Hospital, Oxford

Mrs Sarah Biggs
Former Vice-Chairman of CHILD, Member of the Kings Fund Committee on Counselling

Dr Virginia Bolton
Senior Lecturer, King's College Hospital, London

Professor Peter Braude
Chairman, Divison of Obstetrics & Gynaecology, UMDS of Guy's & St Thomas' Hospitals, London

Mrs Linda Breeze
Counsellor for National Childbirth Trust and RELATE

Mr Peter Brinsden
Medical Director, Bourn Hall, Cambridge

Dr Elizabeth Bryan
Medical Director, Multiple Births Foundation

Mr Chris Chandler
Clinician, Billinge Hospital, Wigan

Dr John Clarke
Leverhulme Emeritus Research Fellow, Zoology Department, Oxford; Formerly Chairman of the Society for the Study of Fertility; Formerly Member of the ILA

Ms Jennifer Clifford
Counsellor, London

Mrs Elizabeth Corrigan
Nursing Director, Department of Obstetrics & Gynaecology, St Michael's Hospital, Bristol

Dr John Coutts
Reader in Reproductive Endocrinology, University of Glasgow

Ms Marilyn Cranshaw
Social Worker, York

Ms Diane Critchlow
Senior Clinical Embryologist, St Mary's Hospital, Manchester

Dr Ruth Curson
Associate Specialist, Assisted Conception Unit, King's College Hospital, London

Ms Karin Dawson
Consultant Embryologist, Hammersmith Hospital, London

Ms Hillary Everett
Social Worker/Counsellor, St Bartholomew's Hospital, London

Dr Simon Fishel
Reader, Obstetrics & Gynaecology, University of Nottingham, Scientific Director, NURTURE

Dr Richard Fleming
Scientist, Glasgow Royal Infirmary

Dr Tom Fleming
Reader, Department of Biology, University of Southampton

Mr Robert Forman
Clinical Director, London Gynaecology & Fertility Centre

Professor Stephen Franks
Professor of Reproductive Endocrinology St Mary's Hospital, London

Professor Lynn Fraser
Professor of Reproductive Biology King's College, London

Ms Ceinwen Gearon
Senior Embryologist, The Lister Hospital, London

Professor Christine Gosden
Professor of Medical Genetics, The Women's Hospital, Liverpool

Dr Mark Hamilton
Consultant Gynaecologist and Obstetrician; Honorary Clinical Lecturer, University of Aberdeen

Mrs Heideh Hillier
IVF Nurse Manager, Edinburgh Assisted Conception Unit

Ms Jennifer Hunt
Senior Infertility Counsellor, Hammersmith Hospital, London

Ms Margaret Inglis
Counsellor, Royal Free Hospital, London

Dr May-Beth Jamieson
Senior Embryologist, University Department of Obstetrics and Gynaecology, Glasgow Royal Infirmary

Mr Richard Kennedy
Consultant Gynaecologist & Obstetrician, Walsgrave Hospital

Ms Janice Kerr
Clinical Nurse Specialist (Infertility), Leeds

Mr Charles Kingsland
Consultant Gynaecologist and Obstetrician; Honorary Lecturer, The Women's Hospital, Liverpool

Dr Martin Lees
Consultant Gynaecologist and Obstetrician; Senior Lecturer, Royal Infirmary of Edinburgh

Dr Henry Leese
Scientist, Department of Biology, University of York

Dr Elizabeth Lenton
Senior Lecturer in Reproductive Endocrinology; Director of Sheffield Fertility Centre

Mr Terry Leonard
Senior Embryologist, Northamptonshire Fertility Services

Dr Alan McDermott
Director, Regional Cytogenetics Centre, Southmead Hospital, Bristol

Dr John Mills
Consultant Gynaecologist & Obstetrician, Ninewells Hospital, Dundee

Dr Jim Monach
Lecturer, University of Sheffield

Dr Alison Murdoch
Consultant Gynaecologist & Obstetrician; Honorary Senior Lecturer, Royal Victoria Infirmary, Newcastle-upon-Tyne

Mr Roger Neuberg
Consultant Gynaecologist & Obstetrician; Director of Infertility Services, Leicester Royal Infirmary

Mr Julian Pampiglione
Consultant Gynaecologist & Obstetrician, The Royal Bournemouth Hospital

Ms Kathryn Parkinson
Unit Manager of IVF & OPD, BMI Portland Hospital, London

Mr John Parsons
Honorary Consultant; Senior Lecturer, King's College Hospital, London

Dr Elizabeth Pease
Clinical Assistant, Regional IVF & DI Unit, St Mary's Hospital, Manchester

Dr Susan Pickering
Senior Research Scientist, Zeneca Pharmaceuticals, Cheshire

Dr David Polson
Senior Registrar of Gynaecology, Hope Hospital, Salford

Ms Barbara Ray
Clinical Scientist, Southmead Hospital, Bristol

Mr John Robinson
Senior Lecturer, Applied Biology; Scientific Director, Hull IVF Unit

Mr Anthony Rutherford
Consultant Gynaecologist & Obstetrician, Leeds General Infirmary

Mr Robert Sawers
Clinician, Birmingham Midlands Women's Hospital

Ms Annette Sayburn
Director of Clinical Services, BMI Portland Hospital, London

Dr Mary Seller
Reader in Development Genetics, Medical & Molecular Genetics, Guy's Hospital, London

Dr Francoise Shenfield
Clinical and Research Assistant, Middlesex University Hospital

Ms Ros Shaw-Smith
Chartered Psychologist, John Radcliffe Maternity Hospital, Oxford

Mr Eric Simons
Medical Director, IVF & Fertility Centre, Cromwell Hospital, London

Ms Jennifer Speirs
Director, Family Care, Edinburgh

Dr Arasaratnam Srikantharasah
Research Embryologist, University of Aberdeen

Dr Bert Stewart
Scientific Director, Midland Fertility Services, Aldridge

Dr Alison Taylor
Senior Registrar; Lecturer, UMDS Guy's & St Thomas' Hospitals, London

Mr Stephen Troup
Senior Clinical Embryologist, Manchester Fertility Services

Mrs Sheila Walker
Senior Lecturer; Honorary Consultant, University Hospital of Wales, Cardiff

Dr Peter Wardle
Consultant Gynaecologist & Obstetrician; Senior Lecturer, University of Bristol

Dr John Waterstone
Senior Registrar, Lewisham Hospital, London

Reverend Professor Paul F Watson
Professor of Reproductive Cryobiology, Royal Veterinary College, London

Dr Christine West
Consultant Gynaecologist & Obstetrician, Royal Infirmary, Edinburgh

Dr Maureen Wood
Senior Scientific Officer, MRC Experimental Embryology & Teratology Unit, London

Mr Robin Yates
Medical Research Director of Assisted Conception Unit, Royal Infirmary, Glasgow

ANNEX 6

HFEA ACCOUNTS 1994/95

Gross Income

• Government grant	458,811
• Income from licensing	886,779
• Income from other sources	8,686
	1,354,276

Transfer from Reserves

	49,190
	1,403,466

Expenditure

• Staff costs	597,365	
• Depreciation	49,190	
• Other operating charges**	676,384	
		1,322,939
Operating Deficit		80,527
Income from Investments		0
Deficit for the Financial Year		80,527
Appropriations		(7,732)
		72,795
Retained surplus brought forward		(21,142)
Retained deficit carried forward		51,653

Other operating charges

Accommodation	208,724
Travel & Subsistence – Employees	7,472
Travel & Subsistence – Members	29,169
Travel & Subsistence – Inspectors	47,018
Attendance Fees – Inspectors	27,749
Professional & Administrative Fees	119,994
Audit Fees	8,029
Register of Information	35,381
Stationery & Printing	92,864
Photocopying Charges	7,281
Telephones & Postage	30,847
Communications	3,673
Training & Staff Development	20,049
Recruitment & Advertising	7,540
Conferences & Meeting Expenses	17,327
Library & Reading Materials	4,857
Sundry Office Equipment	8,447
Miscellaneous	203
Bad Debts	363
Total	676,987

A copy of the Authority's full accounts is available from HMSO.

ANNEX 7

DATA TABLES OF SPECIAL INTEREST

TABLE 1(a)

RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (all centres)

(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	*15197*	*17942*	*14306 (79.7%)*	*3242 (18.1%)*	*2550 (14.2%)*	*3403*
Donated Sperm	*1535*	*1755*	*1578 (89.9%)*	*413 (23.5%)*	*337 (19.2%)*	*463*
Donated Eggs	*89*	*95*	*77 (81.1%)*	*27 (28.4%)*	*20 (21.1%)*	*30*
Donated Embryos	*24*	*25*	*16 (64.0%)*	*8 (32.0%)*	*6 (24.0%)*	*7*
Totals	*16845*	*19817*	*15977 (80.6%)*	*3690 (18.6%)*	*2913 (14.7%)*	*3903*

TABLE 1(b)

RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (large centres)

(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	*13305*	*15802*	*12638 (80.0%)*	*2869 (18.2%)*	*2278 (14.4%)*	*3026*
Donated Sperm	*1333*	*1528*	*1378 (90.2%)*	*359 (23.5%)*	*294 (19.2%)*	*406*
Donated Eggs	*77*	*80*	*66 (82.5%)*	*24 (30.0%)*	*19 (23.8%)*	*29*
Donated Embryos	*19*	*20*	*14 (70.0%)*	*7 (35.0%)*	*5 (25.0%)*	*5*
Totals	*14734*	*17430*	*14096 (80.9%)*	*3259 (18.7%)*	*2596 (14.9%)*	*3466*

TABLE 1(c)

RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (small centres)

(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	*1892*	*2140*	*1668 (77.9%)*	*373 (17.4%)*	*272 (12.7%)*	*377*
Donated Sperm	*202*	*227*	*200 (88.1%)*	*54 (23.8%)*	*43 (18.9%)*	*57*
Donated Eggs	*12*	*15*	*11 (73.3%)*	*3 (20.0%)*	*1 (6.7%)*	*1*
Donated Embryos	*5*	*5*	*2 (40.0%)*	*1 (20.0%)*	*1 (20.0%)*	*2*
Totals	*2111*	*2387*	*1881 (78.8%)*	*431 (18.1%)*	*317 (13.3%)*	*437*

TABLE 2(a)

RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (all centres)

(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	*536*	*595*	*128 (21.5%)*	*19 (3.2%)*	*15 (2.5%)*	*20*
Donated Sperm	*26*	*31*	*12 (38.7%)*	*1 (3.2%)*	*0 (0.0%)*	*0*
Totals	*562*	*626*	*140 (22.4%)*	*20 (3.2%)*	*15 (2.4%)*	*20*

TABLE 2(b)

RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (large centres)

(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	*480*	*538*	*123 (22.9%)*	*18 (3.3%)*	*14 (2.6%)*	*19*
Donated Sperm	*24*	*29*	*12 (41.4%)*	*1 (3.4%)*	*0 (0.0%)*	*0*
Totals	*504*	*567*	*135 (23.8%)*	*19 (3.4%)*	*14 (2.5%)*	*19*

TABLE 2(c)

RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (small centres)

(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	*56*	*57*	*5 (8.8%)*	*1 (1.8%)*	*1 (1.8%)*	*1*
Donated Sperm	*2*	*2*	*0 (0.0%)*	*0 (0.0%)*	*0 (0.0%)*	*0*
Totals	*58*	*59*	*5 (8.5%)*	*1 (1.7%)*	*1 (1.7%)*	*1*

TABLE 3(a)
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (all centres)
(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Donated Eggs	585	666	588 (88.3%)	166 (24.9%)	122 (18.3%)	162
Donated Embryos	94	104	92 (88.5%)	32 (30.8%)	26 (25.0%)	38
Totals	679	770	680 (88.3%)	198 (25.7%)	148 (19.2%)	200

TABLE 3(b)
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (large centres)
(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Donated Eggs	532	602	532 (88.4%)	146 (24.3%)	107 (17.8%)	144
Donated Embryos	82	90	78 (86.7%)	26 (28.9%)	21 (23.3%)	30
Totals	614	692	610 (88.2%)	172 (24.9%)	128 (18.5%)	174

TABLE 3(c)
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (small centres)
(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Donated Eggs	53	64	56 (87.5%)	20 (31.3%)	15 (23.4%)	18
Donated Embryos	12	14	14 (100.0%)	6 (42.9%)	5 (35.7%)	8
Totals	65	78	70 (89.7%)	26 (33.3%)	20 (25.6%)	26

TABLE 4(a)
RESULTS OF FROZEN EMBRYO TRANSFER CYCLES (all centres)
(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	2421	2861	2793 (97.6%)	396 (13.8%)	310 (10.8%)	360
Donated Sperm	266	305	296 (97.0%)	56 (18.4%)	47 (15.4%)	55
Donated Eggs	182	222	220 (99.1%)	38 (17.1%)	28 (12.6%)	34
Donated Embryos	89	107	107 (100.0%)	19 (17.8%)	16 (15.0%)	20
Totals	2958	3495	3416 (97.7%)	509 (14.6%)	401 (11.5%)	469

TABLE 4(b)
RESULTS OF FROZEN EMBRYO TRANSFER CYCLES (large centres)
(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	2121	2509	2450 (97.6%)	351 (14.0%)	279 (11.1%)	324
Donated Sperm	211	242	234 (96.7%)	44 (18.2%)	39 (16.1%)	45
Donated Eggs	164	200	198 (99.0%)	32 (16.0%)	23 (11.5%)	27
Donated Embryos	77	91	91 (100.0%)	16 (17.6%)	14 (15.4%)	18
Totals	2573	3042	2973 (97.7%)	443 (14.6%)	355 (11.7%)	414

TABLE 4(c)
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (small centres)
(all percentages are of number of treatment cycles)

	Patients	*Treatment Cycles*	*Embryo Transfers*	*Clinical Pregnancies*	*Live Births*	*Babies Born*
Own Gametes	300	352	343 (97.4%)	45 (12.8%)	31 (8.8%)	36
Donated Sperm	55	63	62 (98.4%)	12 (19.0%)	8 (12.7%)	10
Donated Eggs	18	22	22 (100.0%)	6 (27.3%)	5 (22.7%)	7
Donated Embryos	12	16	16 (100.0%)	3 (18.8%)	2 (12.5%)	2
Totals	385	453	443 (97.8%)	66 (14.6%)	46 (10.2%)	55

TABLE 5(a)
DI CLINICAL PREGNANCY RATES AND LIVE BIRTH RATES BY NUMBER OF PREVIOUS ATTEMPTS (for all centres)

	0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*10+*
Patients Treated	3005	2683	2256	1877	1651	1416	1163	1017	877	718	612	1242
Pregnancy Rates per cycle%	12.1	10.9	10.0	8.9	9.7	8.2	9.5	9.2	9.6	9.7	9.0	7.9
Live Birth Rates per cycle%	10.0	9.3	8.4	7.6	7.3	6.9	6.8	7.3	7.5	6.8	7.4	6.4

TABLE 5(b)
IVF CLINICAL PREGNANCY RATES AND LIVE BIRTH RATES BY NUMBER OF PREVIOUS ATTEMPTS (for all centres)

	0	*1*	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*10+*
Patients Treated	10459	6158	3194	1647	888	446	296	172	91	56	56	87
Pregnancy Rates per cycle %	19.5	17.3	16.8	16.5	13.7	14.3	14.0	15.4	16.0	12.0	15.7	11.0
Live Birth Rates per cycle %	15.5	13.8	12.6	13.6	10.3	10.5	11.1	11.6	9.3	5.1	14.0	7.3

TABLE 6
NUMBER OF BOYS AND GIRLS BORN FOLLOWING IVF AND DI TREATMENTS

	Boys	*Girls*	*Total*
Donor Insemination	948 (52.5%)	857 (47.5%)	1805
In Vitro Fertilisation	2388 (52.0%)	2204 (48.0%)	4592

TABLE 7(a)
MEAN PREGNANCY AND LIVE BIRTH RATES FOR STIMULATED IVF WITH FRESH EMBRYO TRANSFER CYCLES (all centres)

		Pregnancy Rates %			*Live Birth Rates %*		
	Number of Treatment Cycles	*Per Treatment Cycle (%)*	*Per Egg Collection (%)*	*Per Transfer (%)*	*Per Treatment Cycle (%)*	*Per Egg Collection (%)*	*Per Transfer (%)*
Own Gametes	*17942*	*18.1*	*19.5*	*22.7*	*14.2*	*15.3*	*17.8*
Donated Sperm	*1755*	*23.5*	*23.6*	*26.2*	*19.2*	*19.3*	*21.4*
Donated Eggs	*95*	*28.4*		*35.1*	*21.1*		*26.0*
Donated Embryos	*25*	*32.0*		*50.0*	*24.0*		*37.5*
Totals	*19817*	*18.6*	*19.7*	*23.1*	*14.7*	*15.7*	*18.2*

TABLE 7(b)
MEAN PREGNANCY AND LIVE BIRTH RATES FOR UNSTIMULATED IVF WITH FRESH EMBRYO TRANSFER CYCLES (all centres)

		Pregnancy Rates %			*Live Birth Rates %*		
	Number of Treatment Cycles	*Per Treatment Cycle (%)*	*Per Egg Collection (%)*	*Per Transfer (%)*	*Per Treatment Cycle (%)*	*Per Egg Collection (%)*	*Per Transfer (%)*
Own Gametes	*595*	*3.2*	*9.7*	*14.8*	*2.5*	*7.6*	*11.7*
Donated Sperm	*31*	*3.2*	*6.6*	*8.3*	*0.0*	*0.0*	*0.0*
Donated Eggs	*666*	*24.9*		*28.2*	*18.3*		*20.7*
Donated Embryos	*104*	*30.8*		*34.8*	*25.0*		*28.3*
Totals	*1396*	*15.6*	*9.1*	*26.6*	*11.7*	*4.8*	*19.8*

TABLE 7(c)
MEAN PREGNANCY AND LIVE BIRTH RATES FOR FROZEN EMBRYO TRANSFER CYCLES (all centres)

	Number of Treatment Cycles	Pregnancy Rates Per Treatment Cycle (%)	Live Birth Rates% Per Treatment Cycle (%)
Own Gametes	*2861*	*13.8*	*10.8*
Donated Sperm	*305*	*18.4*	*15.4*
Donated Eggs	*22*	*17.1*	*12.6*
Donated Embryos	*107*	*17.8*	*15.0*
Totals	*3495*	*14.6*	*11.5*

TABLE 8
DEVELOPMENTAL DEFECTS AND SYNDROMES

Chromosomal Syndromes	*Total*	*Fresh IVF*	*Frozen IVF*	*DI*	*Micromanipulation*
Downs' Syndrome	8	5	2	0	1
Other chromosomal abnormalities	4	2	1	1	0
Congenital Abnormalities					
Cleft lip with cleft palate	2	2	0	0	0
Anomalies of the alimentary system	3	3	0	0	0
Cardiac murmurs	8	5	0	3	0
Other congenital cardiac anomalies	8	6	0	2	0
Other anomalies of the cardiac septa	1	0	1	0	0
Anomalies of the umbilical vessels	2	2	0	0	0
Anomalies of the cardiovascular system	1	1	0	0	0
Hypospadias, Epispadias	2	1	0	1	0
Anomalies of the respiratory system	1	1	0	0	0
Anomalies of the male external genitalia	1	0	0	1	0
Anomalies of the musculoskeletal system	1	1	0	0	0
Renal anomalies	4	2	0	2	0
Polydatyly or syndactyly	9	4	0	5	0
Talipes	2	1	1	0	0
Other anomalies of the limbs or limb girdle	1	0	0	1	0
Anomalies of the diaphragm	1	1	0	0	0
Exomphalos	1	1	0	0	0
Other unspecified anomalies	2	2	0	0	0

Some children were born with more than one chromosomal or congenital abnormality.
Out of 6,397 children born from IVF and DI treatment 59 children were born with developmental defects and/or syndromes.

ANNEX 8

INFORMATION AVAILABLE TO THE PUBLIC

The HFEA provides information which is available to prospective patients, interested organisations and the general public. If you require any information, please contact the HFEA by mail or by telephone.

Annual Reports: 1992-96
Code of Practice *(second revision)*
Code of Practice on Enforcement

Consultation documents:

- Sex Selection
- Donated Ovarian Tissue in Embryo Research and Assisted Conception (consultation document and report available)
- The Publication of Centres' Success Rates for In Vitro Fertilisation and Donor Insemination

Information leaflets:

- The Role of the HFEA
- Sperm and Egg Donors and the Law
- *In Vitro* Fertilisation
- Egg Donation
- Treatment Clinics: Questions to Ask
- Donor Insemination
- Embryo Storage
- Consent to the Use and Storage of Gametes and Embryos

List of licensed clinics
The Patients' Guide to DI and IVF Clinics
Videos (on *In Vitro* Fertilisation and Donor Insemination) to be supplied for education purposes only.

ANNEX 9

GLOSSARY OF TERMS

Autosomal
Pertaining to any chromosome that occurs in the nucleus, except for the sex chromosomes.

Chromosome
Small bodies within the nucleus of every cell in the body. They contain the genes.

Clinical pregnancy
Ultrasound evidence of a fetal heart.

Clinical pregnancy rate
This is calculated as a proportion of pregnancies for every 100 treatment cycles commenced.

Congenital abnormalities
Deformities or diseases which are either present at birth or show themselves soon after birth.

Cryopreservation
The freezing of oocytes, spermatozoa or embryos and their storage in liquid nitrogen.

Cystic fibrosis
A disorder of the mucus-secreting glands of the lungs, the pancreas, the mouth and the gastrointestinal tract. The commonest serious genetic disease in Caucasian children.

Directions
The Act allows the Authority to impose additional conditions on licensed activities. These Directions cover areas where primary legislation would be inappropriate because of the need for flexibility. Directions can be applied to an individual clinic or generally.

Donor insemination (DI)
The insemination into a woman of donor sperm (at the cervical opening or into the cervical canal).

Embryo
A fertilised egg up to eight weeks of development. At two weeks it is approximately 1-1.5mm in diameter.

Embryo transfer
The transfer of one or more embryos to the uterus.

Embryologist
A scientist who creates, cultures and studies embryos in a clinical or research laboratory.

Female factor
This term covers any reason why a woman is infertile, such as ovulation failure or damage to the fallopian tubes.

Gamete
The male sperm or the female egg.

Hepatitis
Refers to infection with one of the hepatitis viruses which causes acute or chronic inflammation of the liver cells.

Intra Cytoplasmic Sperm Injection (ICSI)
A micromanipulation technique. A variation of IVF treatment where a single sperm is injected into the inner cellular structure of the egg. This technique is used for couples in which the male partner has severely impaired or few sperm.

Intrauterine insemination (IUI)
The insemination of specially prepared sperm through the cervical canal into the uterine cavity.

***In vitro* fertilisation (IVF)**
Sperm and eggs are collection and put together to achieve fertilisation outside the body. Up to three of the resulting embryos can be transferred into a woman's uterus.

Live birth
The delivery of one or more babies from a pregnancy.

Live birth rate
This is calculated as a proportion of live births for every 100 treatment cycles commenced.

Male factor
This term covers any reason why the male partner's sperm may be less effective or incapable of fertilisation, including the absence of viable sperm and a failed reversal of a vasectomy.

Micromanipluation
This term covers any technique used in IVF to bypass the zona pellucida (protein shell) which surrounds the egg, as this frequently prevents sperm which have poor motility or morphology from penetrating and fertilising the egg.

Miscarriage
Spontaneous complete loss of a pregnancy before 24 weeks.

Multiple birth
Birth of more than one baby from a pregnancy. Such an event is counted as a single live birth outcome for the pregnancy, irrespective of the number of babies.

Multiple birth rate
This rate is calculated as a proportion of all births.

Muscular dystrophy
A hereditary condition where muscles slowly waste away.

Oocyte
Another name for an egg.

Perinatal death
The death of a baby either in the uterus after 24 weeks pregnancy (stillbirth) or within 28 days of the birth.

Preimplantation genetic diagnosis
After IVF, one or two cells are removed from embryos *in vitro* and tested to detect their sex or genetic makeup of the embryo.

Primitive streak
This develops in an embryo by day 14 when the cells which form the fetus separate from those which form the placenta and umbilical cord.

Spermatid
An immature spermatozoan.

Stimulated cycle
A treatment cycle in which the woman's ovaries are stimulated with superovulatory drugs to produce more than one egg.

Sub zonal insemination (SUZI)
A micromanipulation technique. A variation of IVF treatment where a single sperm is deposited just beneath the zona pellucida (protein shell). This technique is aimed at patients who have sperm which fail to penetrate the zona.

Transport (or Satellite) IVF
An arrangement whereby IVF is carried out at a primary centre (HFEA licensed) but other parts of the treatment (eg ovulation induction or egg retrieval) are performed at a secondary centre (not necessarily HFEA licensed). The embryology and embryo transfer takes place at the primary centre.

Treatment cycle
a) IVF with fresh embryos: a cycle begins with the administration of drugs for the purpose of superovulation, or if no drugs are used, with the attempt to collect eggs.
b) IVF with frozen-thawed embryos: a cycle begins with the removal of the stored embryos in order to be thawed and then transferred.

For DI a treatment cycle begins when the first insemination with donor sperm takes place.

Unstimulated ('natural')
No superovulatory drugs were given to stimulate the cycle.

DESIGNED AND PRODUCED BY FIRST IMPRESSION DESIGN